

US3402082 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:25:39

All time stamps listed in this document are displayed in GMT

US3402082

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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Participant ID

US3402082

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

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US3402082

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
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 16:46:51

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	29 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

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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 16:46:51

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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) 26 Apr 2021 01:33:28

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Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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 (3)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Condition	HYPERCHOLESTEROLEMIA
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 (4)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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)	_____

US3402082

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Condition	BILATERAL NEUROPATHY FEET - SENSORY
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	12:32 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:32
Height ( <i>xxx.x</i> )	182.8 cm
Weight ( <i>xxx.x</i> )	92.6 kg
BMI ( <i>xxx.x</i> )	27.71141 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 16:46:51

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:46:51

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:46:51

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 142266

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 16:46:52

Generated On: 09 Jun 2021 17:25:39

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 16:46:52

Generated On: 09 Jun 2021 17:25:39

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)	29 JUL 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:32
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 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 16:46:52

Generated On: 09 Jun 2021 17:25:39

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)	29 JUL 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 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 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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) 29 JUL 2020

What was the treatment time? (00:00-23:59) 13:21 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 13:21

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 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JUL 2020

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

29 JUL 2020 13:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:02	29 JUL 2020 13:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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

98.9 °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 29 JUL 2020 13:56

PC Open Date & Time 29 JUL 2020 13:41

PC Close Date & Time 29 JUL 2020 16:11

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**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 98.7 °F

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

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

PC Time Stamp	29 JUL 2020 20:55
PC Open Date & Time	29 JUL 2020 17:06
PC Close Date & Time	30 JUL 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**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

98.3 °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

30 JUL 2020 19:30

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**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

98.6 °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

31 JUL 2020 20:19

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**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

98.2 °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

01 AUG 2020 20:02

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**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

02 AUG 2020 20:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 19:12

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 19:59

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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

29 JUL 2020 13:56

PC Open Date & Time

29 JUL 2020 13:41

PC Close Date & Time

29 JUL 2020 16:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 20:56

PC Open Date & Time

29 JUL 2020 17:06

PC Close Date & Time

30 JUL 2020 11:59



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 19:31

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 20:19

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 20:03

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**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

02 AUG 2020 20:08

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**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

03 AUG 2020 19:13

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 20:00

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 13:57
PC Open Date & Time	29 JUL 2020 13:41
PC Close Date & Time	29 JUL 2020 16:11



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 17:06

PC Close Date & Time

30 JUL 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**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

50 of 2530

EAB) (1725)

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 19:32
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**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

52 of 2530

EAB) (1725)

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 20:20
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**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 ☒

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 20:04
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**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 ☒

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:09
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

58 of 2530

EAB) (1725)

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 19:13
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

60 of 2530

EAB) (1725)

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:01
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:51

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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

Visit date (dd MMM yyyy)	26 AUG 2020
--------------------------	-------------

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

Folder OID	VISIT2
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US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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)	26 AUG 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:36
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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)	26 AUG 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:08
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

26 AUG 2020

---

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

---



US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:35

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

US3402082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

26 AUG 2020 11:10

US3402082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:03	26 AUG 2020 11:03
Nasopharyngeal Swab 2	No		

US3402082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 11:56

PC Open Date & Time

26 AUG 2020 11:55

PC Close Date & Time

26 AUG 2020 14:25

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 26 AUG 2020 20:00

PC Open Date & Time 26 AUG 2020 15:20

PC Close Date & Time 27 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**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

98.5 °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

27 AUG 2020 19:40

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**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

98.6 °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

29 AUG 2020 19:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:15

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**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.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 19:30

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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

26 AUG 2020 11:56

PC Open Date & Time

26 AUG 2020 11:55

PC Close Date & Time

26 AUG 2020 14:25

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**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

26 AUG 2020 20:00

PC Open Date & Time

26 AUG 2020 15:20

PC Close Date & Time

27 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**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

27 AUG 2020 19:41

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**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

29 AUG 2020 19:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**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

30 AUG 2020 19:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**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

31 AUG 2020 19:16

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**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

01 SEP 2020 19:30

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 11:56
PC Open Date & Time	26 AUG 2020 11:55
PC Close Date & Time	26 AUG 2020 14:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 20:01
PC Open Date & Time	26 AUG 2020 15:20
PC Close Date & Time	27 AUG 2020 11:59



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**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 ☒

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 19:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**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 ☐

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**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

EAB) (1725)

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US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:02
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2530

EAB) (1725)

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:56
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**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 ☒

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:16
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**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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US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:31
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:48

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:49

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:49

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:46:49

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:49

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	VISIT3

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:05 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 08:05
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> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

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.*

US3402082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	22 SEP 2020
Collection time ( <i>00:00-23:59</i> )	08:20 (24 HR)
Collection date and time (derived)	22 SEP 2020 08:20

US3402082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:46:52

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 SEP 2020 14:15:37
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59



US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

07 OCT 2020 08:59:57

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 09:07:51
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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	02 NOV 2020 20:04:24
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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 <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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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="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"/>



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

23 NOV 2020 15:21:44

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 15:57:25
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

07 DEC 2020 08:00:00

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

14 DEC 2020 09:58:07

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

21 DEC 2020 12:22:25

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 09:18:23

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

04 JAN 2021 11:40:54

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 11:44:03

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

18 JAN 2021 14:27:19

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 07:55:54

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 09:00:10
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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	08 FEB 2021 08:53:14
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

15 FEB 2021 06:56:09

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

22 FEB 2021 07:55:52

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

26 FEB 2021 11:57:40

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 14:18:12
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 229

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

16 MAR 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 07:53:57

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

26 MAR 2021 12:59:09

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

03 APR 2021 09:04:47

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

09 APR 2021 19:56:25

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

16 APR 2021 14:55:51

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

23 APR 2021 08:15:35

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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

30 APR 2021 08:35:44

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐ 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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐ 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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59
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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐ 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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐ 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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2021 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 FEB 2022 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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°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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59

US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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°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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59



US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐  
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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**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 ☐

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3402082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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"/>

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3402082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:25:39

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		10 MAR 2021 11:45:26

US3402082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:13:18

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402082

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:13:18

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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	VISIT4



US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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) \_\_\_\_\_

US3402082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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.*

US3402082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00-23:59)	08:47 (24 HR)
Collection date and time (derived)	9 FEB 2021 08:47

US3402082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402082

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3402082**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

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*

**US3402082**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Date of Contact	16 FEB 2021
Time of Contact	12:30
Date and Time of Contact (derived)	16 FEB 2021 12:30
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>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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"/>



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Symptom Day

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

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Symptom Day

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

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021
------	-------------

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

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

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

Temperature	37.2 C
-------------	--------

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

Cough	None	<input 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 16 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021
------	-------------

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

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

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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021
------	-------------

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

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

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

Temperature	97.1 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 16 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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"/>

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Symptom Day

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

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021
------	-------------

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

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

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

Temperature	98.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 FEB 2021
------	-------------

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

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

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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EAB) (1725)

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 16 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 16 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Date of Visit	16 FEB 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	16 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 FEB 2021
Day 5	Yes	20 FEB 2021
Day 7	Yes	22 FEB 2021
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

Visit date (dd MMM yyyy)	16 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	SICKD1
------------	--------

US3402082

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 12:37
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402082

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3402082

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 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 FEB 2021



US3402082

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

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

---

Visit date (dd MMM yyyy)	28 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	UNBLND_DECIDE
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US3402082

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Date of updated informed consent (*dd MMM yyyy*) 06 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3402082

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	13:44 (24 HR)
Collection date and time (derived)	28 JAN 2021 13:44

US3402082

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	13:45
Collection Date and Time (derived)	28 JAN 2021 13:45

US3402082

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:32:19

Generated On: 09 Jun 2021 17:25:39

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

AEID	USA-US059-2021-MRNA-1273-P30 1000008
Adverse event	UNSTABLE BALANCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	3 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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SUBJECT HAS WEAKENED LEFT  
LOWER EXTREMITY, LOST HIS  
BALANCE ON THE ICE AND  
FELL. DUE TO WEAKENED  
EXTREMITY AND ICY  
CONDITION SUBJECT WAS  
UNABLE TO STAND UP. HE  
ENDED UP GOING TO THE  
HOSPITAL TO MAKE SURE  
EVERYTHING WAS OKAY.  
THEY ENDED UP ADMITTING  
HIM AND DOING A FULL WORK  
UP BEING THAT THE SUBJECT  
IS A DIABETIC. SUBJECT DID  
HAVE CBC, CMP, UA,  
TROPONIN LEVEL, MRI BRAIN,  
AND CHEST XRAY, ALL OF  
WHICH WERE NORMAL.  
SARSCOV2 TEST NEGATIVE

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---



US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

AEID

Adverse event

GASTRO INTESTINAL UPSET

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:23:45

Generated On: 09 Jun 2021 17:25:39

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

Yes ☒

No ☐

---

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

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US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication BASAGLER INSULIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 2006	
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) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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 (2)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

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

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

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 (3)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication HYDROXINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 (5)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2005	
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) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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"/>

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 2013	
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"/>

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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 DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 1.2

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)

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 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"/>

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE BALANCE

Dose per administration 50/100

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

If dose unit is Other, specify UG/MG

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 (11)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication FOLIC ACID

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE BALANCE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication DEXTROSE 5%

Prophylaxis Yes ☐  
No ☒

Indication UNSTABLE BALANCE

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

CONTINUOUS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	04 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

Name of Medication VENTOLIN HFA

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISORDER

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 01:33:27

Generated On: 09 Jun 2021 17:25:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:23:46

Generated On: 09 Jun 2021 17:25:39

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:23:45

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	
1 FEB 2021	COMPLETE METABOLIC PROFILE	Adverse Event	
01 FEB 2021	TROPONIN	Adverse Event	
1 FEB 2021	CT HEAD WITHOUT CONTRAST	Adverse Event	
01 FEB 2021	CHEST XRAY 1 VIEW	Adverse Event	
03 FEB 2021	COMPLETE BLOOD COUNT	Adverse Event	
03 FEB 2021	COMPLETE METABOLIC PROFILE	Adverse Event	
01 FEB 2021	URINALYSIS	Adverse Event	
02 FEB 2021	US CAROTID DUPLEX BILATERAL	Adverse Event	
03 FEB 2021	MRI BRAIN	Adverse Event	

US3402082

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:25:39

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

US3402082

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:25:39

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 ☐

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	04/FEB/2021 07:51
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

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:46
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

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	15/MAR/2021 12:33
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

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:48
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



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 01:33:28

Generated On: 09 Jun 2021 17:25:39

SAEID	USA-US059-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	20/APR/2021 10:06
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

US3402082 (Prod: Meridian Clinical Research, LLC)

**US3402082**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:25:39**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'US3402082'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:15

US3402082

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:36:48
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:17

US3402082

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4)	29 Jul 2020 19:36:48

**US3402082**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'SCRN'	System	29 Jul 2020 19:36:48

US3402082

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:17



US3402082

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '58'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:37:10

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'YEARS'	System	29 Jul 2020 19:37:10

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '58'	System	29 Jul 2020 17:51:58

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Male (M)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:37:10

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:37:10

US3402082

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'I'	Tarin Gordon (b) (4)	29 Jul 2020 19:37:10

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:37:10
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:37:10
	Tarin Gordon (b) (4)	
	(b) (4)	



**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:37:10
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 19:37:10

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:37:10

US3402082

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:37:10
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:25:39**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:37:10
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:37:10
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 17:51:58
	(b) (4)	

US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jul 2020'	System	29 Jul 2020 17:51:58



US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2020'	System	29 Jul 2020 17:51:58

**US3402082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:39**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 17:51:58

US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 17:51:58
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:39**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 17:51:58
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 17:51:58
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:39**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 17:51:58
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:25:39**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:17

US3402082

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'I'	System	29 Jul 2020 17:52:01



US3402082

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 17:52:01
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:25:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:37:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
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)	29 Jul 2020 20:38:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:25
Data point term sent to Coder	System	29 Jul 2020 19:38:29
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	29 Jul 2020 19:38:02

US3402082

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2006'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:02

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:38:02
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:02

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:38:02
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:02



**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2006'	System	29 Jul 2020 19:38:02

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2006'	System	29 Jul 2020 19:38:02

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:02

**US3402082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:02

US3402082

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
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)	29 Jul 2020 20:38:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:24
Data point term sent to Coder	System	29 Jul 2020 19:38:29
User entered 'HYPERTENSION'	Tarin Gordon (b) (4)	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:15



**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2010'	System	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2010'	System	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:15

**US3402082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:15

US3402082

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	29 Jul 2020 20:38:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:38:24
Data point term sent to Coder	System	29 Jul 2020 19:39:31
User entered 'HYPERCHOLESTEROLEMIA'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:38:33

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2013'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:33



**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:33

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:38:33
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:38:33
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:38:33
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2013'	System	29 Jul 2020 19:38:33

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2013'	System	29 Jul 2020 19:38:33

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:33

**US3402082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:33



US3402082

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	29 Jul 2020 20:38:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:25
Data point term sent to Coder	System	29 Jul 2020 19:39:31
User entered 'ANXIETY'	Tarin Gordon (b) (4)	29 Jul 2020 19:38:54
	(b) (4)	

US3402082

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN Dec 2019'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:54

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:54

US3402082

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:38:54

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:38:54
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:38:54
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Dec 2019'	System	29 Jul 2020 19:38:54

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2019'	System	29 Jul 2020 19:38:54



**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:54

**US3402082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:38:54

US3402082

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:25
Data point term sent to Coder	System	29 Jul 2020 19:39:30
User entered 'INSOMNIA'	Tarin Gordon (b) (4)	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:39:08
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:39:08
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:39:08
	Tarin Gordon (b) (4)	
	(b) (4)	



**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2010'	System	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2010'	System	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:08

**US3402082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:08

US3402082

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 21:37:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 21:37:20
User closed query 'Per CDM requery: Thank you for updating the Location for the condition, however per query please also update the type of Neuropathy (i.e. sensory or motor) and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:56:05
Data point term sent to Coder	System	01 Oct 2020 16:10:06
Query 'Per CDM requery: Thank you for updating the Location for the condition, however per query please also update the type of Neuropathy (i.e. sensory or motor) and amend as appropriate.' answered with 'SENSORY' (Site from DM).	Traci Hull (b) (4)	01 Oct 2020 16:10:04
Coding entries removed.	Traci Hull (b) (4)	01 Oct 2020 16:09:58
User entered 'BILATERAL NEUROPATHY FEET - SENSORY' reason for change: Per Query Resolution	Traci Hull (b) (4)	01 Oct 2020 16:09:58
User opened query 'Per CDM requery: Thank you for updating the Location for the condition, however per query please also update the type of Neuropathy (i.e. sensory or motor) and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:40:49
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:40:49

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 14:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 14:45:41
Data point term sent to Coder	System	27 Sep 2020 14:45:00
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	27 Sep 2020 14:44:20
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	27 Sep 2020 14:44:16
User entered 'bilateral NEUROPATHY feet' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	27 Sep 2020 14:44:16
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:17:46
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:16:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:16:12
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:38:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:38:24
Data point term sent to Coder	System	29 Jul 2020 19:39:30

US3402082

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:39

[Condition](#)

Audit	User	Time (GMT)
User entered 'NEUROPATHY'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2006'	Tarin Gordon (b) (4)	29 Jul 2020 19:39:27



**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:39:27
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:39:27
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2006'	System	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2006'	System	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:27

**US3402082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:27



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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:28
Data point term sent to Coder	System	29 Jul 2020 19:40:31
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tarin Gordon (b) (4)	29 Jul 2020 19:39:46

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'UN UNK 2005'	Tarin Gordon (b) (4)	29 Jul 2020 19:39:46

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:39:46
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:39:46

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:39:46
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:39:46
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2005'	System	29 Jul 2020 19:39:46

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2005'	System	29 Jul 2020 19:39:46



**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:46

**US3402082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	29 Jul 2020 19:39:46

US3402082

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Lumbar radiculopathy, LLT: Lumbar radiculopathy - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	22 Mar 2021 14:27:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 14:27:53
Data point term sent to Coder	System	22 Mar 2021 14:27:29
User entered 'CHRONIC LUMBAR RADICULOPATHY'	Tammy Kohn (b) (4) (b) (4)	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'UN UNK 2019'	(b) (4) Tammy Kohn (b) (4)	22 Mar 2021 14:26:58

US3402082

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tammy Kohn (b) (4)	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Tammy Kohn (b) (4)	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tammy Kohn (b) (4)	22 Mar 2021 14:26:58



**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2019'	System	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2019'	System	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	22 Mar 2021 14:26:58

**US3402082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	22 Mar 2021 14:26:58

US3402082

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 11:23:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 11:23:12
Data point term sent to Coder	System	15 Apr 2021 11:17:29
User entered 'chronic obstructive pulmonary disease'	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48

US3402082

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'un UNK 2006'	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48

US3402082

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '0'	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48



**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '0'	Jennifer Molstead (b) (4)	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'Jan 2006'	System	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '2006'	System	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	15 Apr 2021 11:16:48

**US3402082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	15 Apr 2021 11:16:48

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:40:47
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	



US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '12:32'	(b) (4)	29 Jul 2020 19:40:47
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '29 Jul 2020 12:32'	System	29 Jul 2020 19:40:47

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '182.8' cm	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
DataPoint set to visible.	(b) (4)	
	System	29 Jul 2020 17:52:01

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	29 Jul 2020 19:40:59
User entered '92.6' kg reason for change: Data Entry Error	System	29 Jul 2020 19:40:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Tarin Gordon (b) (4)	29 Jul 2020 19:40:59
User entered '92.58' (non-conformant).	(b) (4)	29 Jul 2020 19:40:47
DataPoint set to visible.	System	29 Jul 2020 17:52:01

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
Amendment Manager: User entered '27.71141'	System	16 Sep 2020 23:38:10
User entered '27.7'	System	29 Jul 2020 19:40:59
User entered empty.	System	29 Jul 2020 19:40:47
DataPoint set to visible.	System	29 Jul 2020 17:52:01

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'kg/m2'	System	29 Jul 2020 19:40:59
User entered empty.	System	29 Jul 2020 19:40:47
DataPoint set to visible.	System	29 Jul 2020 17:52:01

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered '36.9' C	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	



US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:40:47
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered '74'	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	

**US3402082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'bpm'	System	29 Jul 2020 19:40:47

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered '16'	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'breaths/min'	System	29 Jul 2020 19:40:47

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered '118'	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'mmHg'	System	29 Jul 2020 19:40:47

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:19:41
User entered '62'	Tarin Gordon (b) (4)	29 Jul 2020 19:40:47
	(b) (4)	



US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'mmHg'	System	29 Jul 2020 19:40:47

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36

US3402082

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36

US3402082

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:41:18
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
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)	27 Aug 2020 13:30:08
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:03:58
User entered '29 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:41:18

US3402082

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

[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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

US3402082

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

**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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

US3402082

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

**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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24



US3402082

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

**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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

US3402082

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

[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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

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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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24



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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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Folder: Screening

Form: Risk of Exposure

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**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'I'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:24

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:42:24



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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '0'	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	29 Jul 2020 19:42:24
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:42:35
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:35

US3402082

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:35

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'VISIT1'	System	29 Jul 2020 19:42:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:18

US3402082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:15:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:15:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 16:54:18
User entered '142266' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:18



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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:54:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:39

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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:46

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:42:46
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:25:39**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:46

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:25:39**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:42:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '182.8' cm	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '92.6' kg	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '182.8' cm	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '92.6' kg	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:25:39**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '12:32'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '29 Jul 2020 12:32'	System	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '36.9' C	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '74'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'bpm'	System	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '16'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'breaths/min'	System	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '118'	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	29 Jul 2020 19:44:16



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '62'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '182.8' cm	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 01:20:00
User entered '92.6' kg	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:44:16

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
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)	14 Aug 2020 19:00:25
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)	29 Jul 2020 19:44:31
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).		29 Jul 2020 19:44:16
User entered '13:55'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:44:16



US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '29 Jul 2020 13:55'	System	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '37.1' C	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Oral (Oral)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '66'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'bpm'	System	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '16'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'breaths/min'	System	29 Jul 2020 19:44:16



US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '118'	(b) (4)	29 Jul 2020 19:44:16
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '64'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:44:16
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	29 Jul 2020 19:44:16

US3402082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:45:58
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:45:58
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21
	(b) (4)	



US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '13:21'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '29 Jul 2020 13:21'	System	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Right Arm (RIGHT ARM)'	Tarin Gordon (b) (4)	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'ONCE'	System	29 Jul 2020 17:52:21

US3402082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 17:52:21



US3402082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:46:21
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:46:21
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '13:05'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:46:21
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '29 Jul 2020 13:05'	System	29 Jul 2020 19:46:21

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '29 Jul 2020'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:46:38
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:46:38

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:46:38
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:39**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '13:02'	Tarin Gordon (b) (4)	29 Jul 2020 19:46:38



**US3402082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '29 Jul 2020 13:02'	System	29 Jul 2020 19:46:38

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:46:38

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:46:38
	(b) (4)	

US3402082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:46:38

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered empty.	System	29 Jul 2020 19:46:38

US3402082

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 19:46:43

**US3402082**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	29 Jul 2020 19:46:43

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:55:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ee0668e9-97e0-4dab-b174-704ad3e9480e'	System	29 Jul 2020 17:56:13
User entered 'Yes (Y)'	System	29 Jul 2020 17:56:13

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:55:52', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ee0668e9-97e0-4dab-b174-704ad3e9480e'	System	29 Jul 2020 17:56:13
User entered '98.9'	System	29 Jul 2020 17:56:13

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:00', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ee0668e9-97e0-4dab-b174-704ad3e9480e'	System	29 Jul 2020 17:56:13
User entered 'No (N)'	System	29 Jul 2020 17:56:13

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:10', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ee0668e9-97e0-4dab-b174-704ad3e9480e'	System	29 Jul 2020 17:56:13
User entered '29 Jul 2020 13:56'	System	29 Jul 2020 17:56:13

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 13:41'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 16:11'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:54:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a3ca5c6e-dad5-40fc-9167-26423394f7a4'	System	30 Jul 2020 00:55:28
User entered 'Yes (Y)'	System	30 Jul 2020 00:55:28



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a3ca5c6e-dad5-40fc-9167-26423394f7a4'	System	30 Jul 2020 00:55:28
User entered '98.7'	System	30 Jul 2020 00:55:28

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:13', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a3ca5c6e-dad5-40fc-9167-26423394f7a4'	System	30 Jul 2020 00:55:28
User entered 'No (N)'	System	30 Jul 2020 00:55:28

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a3ca5c6e-dad5-40fc-9167-26423394f7a4'	System	30 Jul 2020 00:55:28
User entered '29 Jul 2020 20:55'	System	30 Jul 2020 00:55:28

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 17:06'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 2'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:29:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'effb1d87-d375-46b0-9d33-b1fc775568a9'	System	30 Jul 2020 23:30:41
User entered 'Yes (Y)'	System	30 Jul 2020 23:30:41

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:30:19', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'effb1d87-d375-46b0-9d33-b1fc775568a9'	System	30 Jul 2020 23:30:41
User entered '98.3'	System	30 Jul 2020 23:30:41



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:30:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'effb1d87-d375-46b0-9d33-b1fc775568a9'	System	30 Jul 2020 23:30:41
User entered 'No (N)'	System	30 Jul 2020 23:30:41

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:30:38', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'effb1d87-d375-46b0-9d33-b1fc775568a9'	System	30 Jul 2020 23:30:41
User entered '30 Jul 2020 19:30'	System	30 Jul 2020 23:30:41

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 3'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:00', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8b1ed7d0-0bc6-4485-aab4-d374410567df'	System	01 Aug 2020 00:19:24
User entered 'Yes (Y)'	System	01 Aug 2020 00:19:24

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8b1ed7d0-0bc6-4485-aab4-d374410567df' User entered '98.6'	System	01 Aug 2020 00:19:24

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8b1ed7d0-0bc6-4485-aab4-d374410567df'	System	01 Aug 2020 00:19:24
User entered 'No (N)'	System	01 Aug 2020 00:19:24



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8b1ed7d0-0bc6-4485-aab4-d374410567df'	System	01 Aug 2020 00:19:24
User entered '31 Jul 2020 20:19'	System	01 Aug 2020 00:19:24

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 4'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '3b192b41-424f-447f-b6e7-5446c5fa5110'	System	02 Aug 2020 00:02:39
User entered 'Yes (Y)'	System	02 Aug 2020 00:02:39

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:21', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '3b192b41-424f-447f-b6e7-5446c5fa5110'	System	02 Aug 2020 00:02:39
User entered '98.2'	System	02 Aug 2020 00:02:39

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:30', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '3b192b41-424f-447f-b6e7-5446c5fa5110'	System	02 Aug 2020 00:02:39
User entered 'No (N)'	System	02 Aug 2020 00:02:39

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '3b192b41-424f-447f-b6e7-5446c5fa5110'	System	02 Aug 2020 00:02:39
User entered '01 Aug 2020 20:02'	System	02 Aug 2020 00:02:39



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 5'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:07:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0d139d06-ac2d-4ba8-a1c2-dc104c8f558e'	System	03 Aug 2020 00:08:03
User entered 'Yes (Y)'	System	03 Aug 2020 00:08:03

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:07:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0d139d06-ac2d-4ba8-a1c2-dc104c8f558e'	System	03 Aug 2020 00:08:03
User entered '98.2'	System	03 Aug 2020 00:08:03

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:07:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0d139d06-ac2d-4ba8-a1c2-dc104c8f558e'	System	03 Aug 2020 00:08:03
User entered 'No (N)'	System	03 Aug 2020 00:08:03

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:07:54', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0d139d06-ac2d-4ba8-a1c2-dc104c8f558e'	System	03 Aug 2020 00:08:03
User entered '02 Aug 2020 20:07'	System	03 Aug 2020 00:08:03

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 6'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '18f036b9-38b2-4b5e-9c63-f1a12d1687d7'	System	03 Aug 2020 23:12:48
User entered 'Yes (Y)'	System	03 Aug 2020 23:12:48

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '18f036b9-38b2-4b5e-9c63-f1a12d1687d7'	System	03 Aug 2020 23:12:48
User entered '98.5'	System	03 Aug 2020 23:12:48

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '18f036b9-38b2-4b5e-9c63-f1a12d1687d7'	System	03 Aug 2020 23:12:48
User entered 'No (N)'	System	03 Aug 2020 23:12:48

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '18f036b9-38b2-4b5e-9c63-f1a12d1687d7'	System	03 Aug 2020 23:12:48
User entered '03 Aug 2020 19:12'	System	03 Aug 2020 23:12:48

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 7'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T19:59:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c01a464-3447-4c64-9059-5a0120daf3fd'	System	05 Aug 2020 00:00:04
User entered 'Yes (Y)'	System	05 Aug 2020 00:00:04

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T19:59:48', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c01a464-3447-4c64-9059-5a0120daf3fd'	System	05 Aug 2020 00:00:04
User entered '98.6'	System	05 Aug 2020 00:00:04

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T19:59:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c01a464-3447-4c64-9059-5a0120daf3fd'	System	05 Aug 2020 00:00:04
User entered 'No (N)'	System	05 Aug 2020 00:00:04

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T19:59:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c01a464-3447-4c64-9059-5a0120daf3fd'	System	05 Aug 2020 00:00:04
User entered '04 Aug 2020 19:59'	System	05 Aug 2020 00:00:04

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c39c63d-641c-46bd-b2e1-424e070b3863'	System	29 Jul 2020 17:56:57
User entered 'None (1)'	System	29 Jul 2020 17:56:57

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c39c63d-641c-46bd-b2e1-424e070b3863'	System	29 Jul 2020 17:56:57
User entered 'No (N)'	System	29 Jul 2020 17:56:57

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:34', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c39c63d-641c-46bd-b2e1-424e070b3863'	System	29 Jul 2020 17:56:57
User entered 'No (N)'	System	29 Jul 2020 17:56:57

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c39c63d-641c-46bd-b2e1-424e070b3863'	System	29 Jul 2020 17:56:57
User entered 'None (1)'	System	29 Jul 2020 17:56:57

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0c39c63d-641c-46bd-b2e1-424e070b3863'	System	29 Jul 2020 17:56:57
User entered '29 Jul 2020 13:56'	System	29 Jul 2020 17:56:57

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 13:41'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 16:11'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:48', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '02cc954c-43e8-4a63-83be-9ab6cb19d921'	System	30 Jul 2020 00:56:41
User entered 'None (1)'	System	30 Jul 2020 00:56:41

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '02cc954c-43e8-4a63-83be-9ab6cb19d921'	System	30 Jul 2020 00:56:41
User entered 'No (N)'	System	30 Jul 2020 00:56:41

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:55:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '02cc954c-43e8-4a63-83be-9ab6cb19d921'	System	30 Jul 2020 00:56:41
User entered 'No (N)'	System	30 Jul 2020 00:56:41

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:56:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '02cc954c-43e8-4a63-83be-9ab6cb19d921'	System	30 Jul 2020 00:56:41
User entered 'None (1)'	System	30 Jul 2020 00:56:41

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T20:56:38', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '02cc954c-43e8-4a63-83be-9ab6cb19d921'	System	30 Jul 2020 00:56:41
User entered '29 Jul 2020 20:56'	System	30 Jul 2020 00:56:41

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 17:06'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 2'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:30:56', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7c0f9508-2c6d-4e34-8eb8-80af8c927989'	System	30 Jul 2020 23:31:28
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 23:31:28

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:01', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7c0f9508-2c6d-4e34-8eb8-80af8c927989'	System	30 Jul 2020 23:31:28
User entered 'No (N)'	System	30 Jul 2020 23:31:28

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7c0f9508-2c6d-4e34-8eb8-80af8c927989'	System	30 Jul 2020 23:31:28
User entered 'No (N)'	System	30 Jul 2020 23:31:28

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7c0f9508-2c6d-4e34-8eb8-80af8c927989'	System	30 Jul 2020 23:31:28
User entered 'None (1)'	System	30 Jul 2020 23:31:28

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7c0f9508-2c6d-4e34-8eb8-80af8c927989'	System	30 Jul 2020 23:31:28
User entered '30 Jul 2020 19:31'	System	30 Jul 2020 23:31:28

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 3'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '095cf512-b6c8-4864-989d-cce3277d1b21'	System	01 Aug 2020 00:20:03
User entered 'None (1)'	System	01 Aug 2020 00:20:03

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '095cf512-b6c8-4864-989d-cce3277d1b21'	System	01 Aug 2020 00:20:03
User entered 'No (N)'	System	01 Aug 2020 00:20:03

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '095cf512-b6c8-4864-989d-cce3277d1b21'	System	01 Aug 2020 00:20:03
User entered 'No (N)'	System	01 Aug 2020 00:20:03

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '095cf512-b6c8-4864-989d-cce3277d1b21'	System	01 Aug 2020 00:20:03
User entered 'None (1)'	System	01 Aug 2020 00:20:03

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:19:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '095cf512-b6c8-4864-989d-cce3277d1b21'	System	01 Aug 2020 00:20:03
User entered '31 Jul 2020 20:19'	System	01 Aug 2020 00:20:03

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 4'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb51fc8c-0019-4c37-b908-f0842771adf9'	System	02 Aug 2020 00:03:11
User entered 'None (1)'	System	02 Aug 2020 00:03:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb51fc8c-0019-4c37-b908-f0842771adf9'	System	02 Aug 2020 00:03:11
User entered 'No (N)'	System	02 Aug 2020 00:03:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:02:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb51fc8c-0019-4c37-b908-f0842771adf9'	System	02 Aug 2020 00:03:11
User entered 'No (N)'	System	02 Aug 2020 00:03:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb51fc8c-0019-4c37-b908-f0842771adf9'	System	02 Aug 2020 00:03:11
User entered 'None (1)'	System	02 Aug 2020 00:03:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:08', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb51fc8c-0019-4c37-b908-f0842771adf9'	System	02 Aug 2020 00:03:11
User entered '01 Aug 2020 20:03'	System	02 Aug 2020 00:03:11

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 5'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6712b3eb-7ef6-493e-8ccf-141dda03fde1'	System	03 Aug 2020 00:08:29
User entered 'None (1)'	System	03 Aug 2020 00:08:29

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:08', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6712b3eb-7ef6-493e-8ccf-141dda03fde1'	System	03 Aug 2020 00:08:29
User entered 'No (N)'	System	03 Aug 2020 00:08:29

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6712b3eb-7ef6-493e-8ccf-141dda03fde1'	System	03 Aug 2020 00:08:29
User entered 'No (N)'	System	03 Aug 2020 00:08:29

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6712b3eb-7ef6-493e-8ccf-141dda03fde1'	System	03 Aug 2020 00:08:29
User entered 'None (1)'	System	03 Aug 2020 00:08:29

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6712b3eb-7ef6-493e-8ccf-141dda03fde1'	System	03 Aug 2020 00:08:29
User entered '02 Aug 2020 20:08'	System	03 Aug 2020 00:08:29

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 6'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:52', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '85e84f20-3917-4ed9-88ca-3e4a8aa96e80'	System	03 Aug 2020 23:13:14
User entered 'None (1)'	System	03 Aug 2020 23:13:14

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:12:56', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '85e84f20-3917-4ed9-88ca-3e4a8aa96e80'	System	03 Aug 2020 23:13:14
User entered 'No (N)'	System	03 Aug 2020 23:13:14

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:01', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '85e84f20-3917-4ed9-88ca-3e4a8aa96e80'	System	03 Aug 2020 23:13:14
User entered 'No (N)'	System	03 Aug 2020 23:13:14

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '85e84f20-3917-4ed9-88ca-3e4a8aa96e80'	System	03 Aug 2020 23:13:14
User entered 'None (1)'	System	03 Aug 2020 23:13:14

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:10', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '85e84f20-3917-4ed9-88ca-3e4a8aa96e80'	System	03 Aug 2020 23:13:14
User entered '03 Aug 2020 19:13'	System	03 Aug 2020 23:13:14

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 7'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1a536f90-6622-45a6-9642-90e917a112ea'	System	05 Aug 2020 00:00:37
User entered 'None (1)'	System	05 Aug 2020 00:00:37

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1a536f90-6622-45a6-9642-90e917a112ea'	System	05 Aug 2020 00:00:37
User entered 'No (N)'	System	05 Aug 2020 00:00:37

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:20', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1a536f90-6622-45a6-9642-90e917a112ea'	System	05 Aug 2020 00:00:37
User entered 'No (N)'	System	05 Aug 2020 00:00:37

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:30', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1a536f90-6622-45a6-9642-90e917a112ea'	System	05 Aug 2020 00:00:37
User entered 'None (1)'	System	05 Aug 2020 00:00:37

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:34', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1a536f90-6622-45a6-9642-90e917a112ea'	System	05 Aug 2020 00:00:37
User entered '04 Aug 2020 20:00'	System	05 Aug 2020 00:00:37

US3402082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:56:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:02', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:18', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:21', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'None (0)'	System	29 Jul 2020 17:57:40

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered 'No (N)'	System	29 Jul 2020 17:57:40

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-29T13:57:37', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '67d9e469-8663-4518-bc02-caeabc2b8d45'	System	29 Jul 2020 17:57:40
User entered '29 Jul 2020 13:57'	System	29 Jul 2020 17:57:40



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 13:41'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 16:11'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Jul 2020 17:06'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 2'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:31:55', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:32:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:32:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:32:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'None (0)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:32:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered 'No (N)'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-30T19:32:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'bea316b2-6b36-4efa-872e-47c140b6f05d'	System	30 Jul 2020 23:32:35
User entered '30 Jul 2020 19:32'	System	30 Jul 2020 23:32:35

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 3'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:13', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:30', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:34', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'None (0)'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered 'No (N)'	System	01 Aug 2020 00:20:48



**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-07-31T20:20:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0ebeb2de-681e-42ba-8fc4-9b9eec7c9d5d'	System	01 Aug 2020 00:20:48
User entered '31 Jul 2020 20:20'	System	01 Aug 2020 00:20:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 4'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:18', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:32', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'None (0)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:03:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered 'No (N)'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-01T20:04:07', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e27ab6de-02eb-497b-9d56-eea22cd9a9ee'	System	02 Aug 2020 00:04:09
User entered '01 Aug 2020 20:04'	System	02 Aug 2020 00:04:09

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 5'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:32', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:36', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:52', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'None (0)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:08:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered 'No (N)'	System	03 Aug 2020 00:09:07

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-02T20:09:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a1a5d90f-3943-4e6a-892b-e9d29446875b'	System	03 Aug 2020 00:09:07
User entered '02 Aug 2020 20:09'	System	03 Aug 2020 00:09:07

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:52:21



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 6'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:32', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'None (0)'	System	03 Aug 2020 23:13:48



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe'	System	03 Aug 2020 23:13:48
User entered 'No (N)'	System	03 Aug 2020 23:13:48

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-03T19:13:44', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7b3e96f3-a425-43c0-8a5a-56f3253f93fe' User entered '03 Aug 2020 19:13'	System	03 Aug 2020 23:13:48
	System	03 Aug 2020 23:13:48

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 7'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:42', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:00:57', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30



US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:08', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:11', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:13', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'None (0)'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:18', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered 'No (N)'	System	05 Aug 2020 00:01:30

**US3402082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-04T20:01:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '22b1a7aa-602d-4dbd-bb4b-57d6d990f4b1'	System	05 Aug 2020 00:01:30
User entered '04 Aug 2020 20:01'	System	05 Aug 2020 00:01:30

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:52:21

US3402082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:52:21

**US3402082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	13 Aug 2020 16:57:26



**US3402082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '5 Aug 2020'	Traci Hull (b) (4)	13 Aug 2020 16:57:26

US3402082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	13 Aug 2020 16:57:26

**US3402082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	Traci Hull (b) (4)	13 Aug 2020 16:57:26

US3402082

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	13 Aug 2020 16:57:31

US3402082

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	13 Aug 2020 16:57:31

**US3402082**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	13 Aug 2020 16:57:44

**US3402082**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered '12 Aug 2020'	Traci Hull (b) (4)	13 Aug 2020 16:57:44

US3402082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	13 Aug 2020 16:57:44



US3402082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered empty.	Traci Hull (b) (4)	13 Aug 2020 16:57:44

US3402082

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	13 Aug 2020 16:57:51

US3402082

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	13 Aug 2020 16:57:51

**US3402082**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	20 Aug 2020 11:41:05

**US3402082**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered '19 Aug 2020'	Traci Hull (b) (4)	20 Aug 2020 11:41:05

US3402082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	20 Aug 2020 11:41:05

US3402082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered empty.	Traci Hull (b) (4)	20 Aug 2020 11:41:05

US3402082

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 19:03:42
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 19:03:37
User entered 'Yes (Y)'	Traci Hull (b) (4)	20 Aug 2020 11:41:37



US3402082

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '1'	System	26 Aug 2020 19:03:42
User entered empty.	System	26 Aug 2020 19:03:37
User entered '1'	System	20 Aug 2020 11:41:37

US3402082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:03:58

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:03:58
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	26 Aug 2020 19:03:58

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'VISIT2'	System	26 Aug 2020 19:03:58

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43



US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '10:36'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '26 Aug 2020 10:36'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '36.9' C	Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '80'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'bpm'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '18'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43



US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'breaths/min'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '126'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '72'	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:05:43
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43
	(b) (4)	



US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '12:08'	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:05:43
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '26 Aug 2020 12:08'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '36.7' C	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:05:43
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '92'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'bpm'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '18'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43



US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'breaths/min'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '128'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '68'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:05:43

US3402082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	26 Aug 2020 19:05:43

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:25:39**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:05:49
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:05:49
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23



US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '11:35'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '26 Aug 2020 11:35'	System	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'ONCE'	System	26 Aug 2020 15:42:23



US3402082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:42:23

US3402082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:06:12

US3402082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:06:12

US3402082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '11:10'	(b) (4)	
	Traci Hull (b) (4)	26 Aug 2020 19:06:12
	(b) (4)	

US3402082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '26 Aug 2020 11:10'	System	26 Aug 2020 19:06:12

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:25:39**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '26 Aug 2020'	Traci Hull (b) (4)	26 Aug 2020 19:06:27

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:06:27

US3402082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:06:27



**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:39**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '11:03'	Traci Hull (b) (4)	26 Aug 2020 19:06:27

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '26 Aug 2020 11:03'	System	26 Aug 2020 19:06:27

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:06:27

US3402082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 19:06:40
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Aug 2020 19:06:27

US3402082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	26 Aug 2020 19:06:40
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	26 Aug 2020 19:06:40
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:06:27
User entered empty.	Traci Hull (b) (4)	26 Aug 2020 19:06:27
	(b) (4)	

**US3402082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered empty.	System	26 Aug 2020 19:06:27

US3402082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 19:06:51

US3402082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	26 Aug 2020 19:06:51



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:55:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ea56ee90-70b3-46fe-90cc-e4af4f2bc975'	System	26 Aug 2020 15:56:08
User entered 'Yes (Y)'	System	26 Aug 2020 15:56:08

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:55:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ea56ee90-70b3-46fe-90cc-e4af4f2bc975'	System	26 Aug 2020 15:56:08
User entered '98.0'	System	26 Aug 2020 15:56:08

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:01', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ea56ee90-70b3-46fe-90cc-e4af4f2bc975'	System	26 Aug 2020 15:56:08
User entered 'No (N)'	System	26 Aug 2020 15:56:08

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ea56ee90-70b3-46fe-90cc-e4af4f2bc975'	System	26 Aug 2020 15:56:08
User entered '26 Aug 2020 11:56'	System	26 Aug 2020 15:56:08

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 11:55'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:42:23



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T19:59:48', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd7728835-60f4-4073-ba1d-f019b900aefc'	System	27 Aug 2020 00:00:32
User entered 'Yes (Y)'	System	27 Aug 2020 00:00:32

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:10', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd7728835-60f4-4073-ba1d-f019b900aefc'	System	27 Aug 2020 00:00:32
User entered '98.7'	System	27 Aug 2020 00:00:32

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd7728835-60f4-4073-ba1d-f019b900aefc'	System	27 Aug 2020 00:00:32
User entered 'No (N)'	System	27 Aug 2020 00:00:32

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd7728835-60f4-4073-ba1d-f019b900aefc'	System	27 Aug 2020 00:00:32
User entered '26 Aug 2020 20:00'	System	27 Aug 2020 00:00:32

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 2'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:40:20', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fcc6d037-a230-4b90-865d-7118ffb76d57'	System	27 Aug 2020 23:40:48
User entered 'Yes (Y)'	System	27 Aug 2020 23:40:48



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:40:32', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fcc6d037-a230-4b90-865d-7118ffb76d57'	System	27 Aug 2020 23:40:48
User entered '98.5'	System	27 Aug 2020 23:40:48

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:40:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fcc6d037-a230-4b90-865d-7118ffb76d57'	System	27 Aug 2020 23:40:48
User entered 'No (N)'	System	27 Aug 2020 23:40:48

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:40:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fcc6d037-a230-4b90-865d-7118ffb76d57'	System	27 Aug 2020 23:40:48
User entered '27 Aug 2020 19:40'	System	27 Aug 2020 23:40:48

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 3'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 4'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:00:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7cad1bb8-2435-4b86-b30d-80216432835d'	System	29 Aug 2020 23:01:09
User entered 'Yes (Y)'	System	29 Aug 2020 23:01:09



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:00:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7cad1bb8-2435-4b86-b30d-80216432835d' User entered '98.6'	System	29 Aug 2020 23:01:09

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:00:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7cad1bb8-2435-4b86-b30d-80216432835d'	System	29 Aug 2020 23:01:09
User entered 'No (N)'	System	29 Aug 2020 23:01:09

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '7cad1bb8-2435-4b86-b30d-80216432835d' User entered '29 Aug 2020 19:01'	System	29 Aug 2020 23:01:09

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 5'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:54:42', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8d91d892-ae1a-499d-abbc-93501ca57051'	System	30 Aug 2020 23:55:11
User entered 'Yes (Y)'	System	30 Aug 2020 23:55:11

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:54:52', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8d91d892-ae1a-499d-abb0-93501ca57051'	System	30 Aug 2020 23:55:11
User entered '97.5'	System	30 Aug 2020 23:55:11



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:54:57', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8d91d892-ae1a-499d-abbc-93501ca57051'	System	30 Aug 2020 23:55:11
User entered 'No (N)'	System	30 Aug 2020 23:55:11

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '8d91d892-ae1a-499d-abbc-93501ca57051'	System	30 Aug 2020 23:55:11
User entered '30 Aug 2020 19:55'	System	30 Aug 2020 23:55:11

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 6'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd029c015-043e-4e8e-b9e9-67ef364d18e9'	System	31 Aug 2020 23:15:54
User entered 'Yes (Y)'	System	31 Aug 2020 23:15:54

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:36', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd029c015-043e-4e8e-b9e9-67ef364d18e9'	System	31 Aug 2020 23:15:54
User entered '98.5'	System	31 Aug 2020 23:15:54

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd029c015-043e-4e8e-b9e9-67ef364d18e9'	System	31 Aug 2020 23:15:54
User entered 'No (N)'	System	31 Aug 2020 23:15:54



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd029c015-043e-4e8e-b9e9-67ef364d18e9'	System	31 Aug 2020 23:15:54
User entered '31 Aug 2020 19:15'	System	31 Aug 2020 23:15:54

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 7'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:07', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc08948e-8b0e-40c2-8702-48c2fa81f943'	System	01 Sep 2020 23:30:29
User entered 'Yes (Y)'	System	01 Sep 2020 23:30:29

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:15', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc08948e-8b0e-40c2-8702-48c2fa81f943'	System	01 Sep 2020 23:30:29
User entered '97.6'	System	01 Sep 2020 23:30:29

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:20', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc08948e-8b0e-40c2-8702-48c2fa81f943'	System	01 Sep 2020 23:30:29
User entered 'No (N)'	System	01 Sep 2020 23:30:29

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc08948e-8b0e-40c2-8702-48c2fa81f943'	System	01 Sep 2020 23:30:29
User entered '01 Sep 2020 19:30'	System	01 Sep 2020 23:30:29



US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '64da258a-a417-40f2-8fef-dff936cf7e16'	System	26 Aug 2020 15:56:22
User entered 'None (1)'	System	26 Aug 2020 15:56:22

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:11', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '64da258a-a417-40f2-8fef-dff936cf7e16'	System	26 Aug 2020 15:56:22
User entered 'No (N)'	System	26 Aug 2020 15:56:22

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:13', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '64da258a-a417-40f2-8fef-dff936cf7e16'	System	26 Aug 2020 15:56:22
User entered 'No (N)'	System	26 Aug 2020 15:56:22

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:15', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '64da258a-a417-40f2-8fef-dff936cf7e16'	System	26 Aug 2020 15:56:22
User entered 'None (1)'	System	26 Aug 2020 15:56:22

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '64da258a-a417-40f2-8fef-dff936cf7e16'	System	26 Aug 2020 15:56:22
User entered '26 Aug 2020 11:56'	System	26 Aug 2020 15:56:22



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 11:55'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:34', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '55989427-0df0-4451-b862-cc228daa9cd1'	System	27 Aug 2020 00:00:58
User entered 'None (1)'	System	27 Aug 2020 00:00:58

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '55989427-0df0-4451-b862-cc228daa9cd1'	System	27 Aug 2020 00:00:58
User entered 'No (N)'	System	27 Aug 2020 00:00:58

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:44', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '55989427-0df0-4451-b862-cc228daa9cd1'	System	27 Aug 2020 00:00:58
User entered 'No (N)'	System	27 Aug 2020 00:00:58

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '55989427-0df0-4451-b862-cc228daa9cd1'	System	27 Aug 2020 00:00:58
User entered 'None (1)'	System	27 Aug 2020 00:00:58

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:00:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '55989427-0df0-4451-b862-cc228daa9cd1'	System	27 Aug 2020 00:00:58
User entered '26 Aug 2020 20:00'	System	27 Aug 2020 00:00:58



**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 2'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:01', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e47cb4b4-a8da-4bf6-b268-9c7cfbc1006f'	System	27 Aug 2020 23:41:23
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 23:41:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e47cb4b4-a8da-4bf6-b268-9c7cfbc1006f'	System	27 Aug 2020 23:41:23
User entered 'No (N)'	System	27 Aug 2020 23:41:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e47cb4b4-a8da-4bf6-b268-9c7cfbc1006f'	System	27 Aug 2020 23:41:23
User entered 'No (N)'	System	27 Aug 2020 23:41:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e47cb4b4-a8da-4bf6-b268-9c7cfbc1006f'	System	27 Aug 2020 23:41:23
User entered 'None (1)'	System	27 Aug 2020 23:41:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:18', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e47cb4b4-a8da-4bf6-b268-9c7cfbc1006f' User entered '27 Aug 2020 19:41'	System	27 Aug 2020 23:41:23



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 3'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 4'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:11', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0e98dac0-2e72-407c-8d42-92e0d7c67216'	System	29 Aug 2020 23:01:32
User entered 'None (1)'	System	29 Aug 2020 23:01:32

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:16', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0e98dac0-2e72-407c-8d42-92e0d7c67216'	System	29 Aug 2020 23:01:32
User entered 'No (N)'	System	29 Aug 2020 23:01:32

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:20', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0e98dac0-2e72-407c-8d42-92e0d7c67216'	System	29 Aug 2020 23:01:32
User entered 'No (N)'	System	29 Aug 2020 23:01:32



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0e98dac0-2e72-407c-8d42-92e0d7c67216'	System	29 Aug 2020 23:01:32
User entered 'None (1)'	System	29 Aug 2020 23:01:32

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0e98dac0-2e72-407c-8d42-92e0d7c67216'	System	29 Aug 2020 23:01:32
User entered '29 Aug 2020 19:01'	System	29 Aug 2020 23:01:32

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 5'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:13', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1ae09af0-d465-41fa-9a4f-fd1210cef538'	System	30 Aug 2020 23:55:35
User entered 'None (1)'	System	30 Aug 2020 23:55:35

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:17', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1ae09af0-d465-41fa-9a4f-fd1210cef538'	System	30 Aug 2020 23:55:35
User entered 'No (N)'	System	30 Aug 2020 23:55:35

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1ae09af0-d465-41fa-9a4f-fd1210cef538'	System	30 Aug 2020 23:55:35
User entered 'No (N)'	System	30 Aug 2020 23:55:35



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1ae09af0-d465-41fa-9a4f-fd1210cef538'	System	30 Aug 2020 23:55:35
User entered 'None (1)'	System	30 Aug 2020 23:55:35

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1ae09af0-d465-41fa-9a4f-fd1210cef538'	System	30 Aug 2020 23:55:35
User entered '30 Aug 2020 19:55'	System	30 Aug 2020 23:55:35

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 6'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:56', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd139887b-8bd8-426e-8e3b-791126db88bd'	System	31 Aug 2020 23:16:20
User entered 'None (1)'	System	31 Aug 2020 23:16:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:15:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd139887b-8bd8-426e-8e3b-791126db88bd'	System	31 Aug 2020 23:16:20
User entered 'No (N)'	System	31 Aug 2020 23:16:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd139887b-8bd8-426e-8e3b-791126db88bd'	System	31 Aug 2020 23:16:20
User entered 'No (N)'	System	31 Aug 2020 23:16:20



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd139887b-8bd8-426e-8e3b-791126db88bd'	System	31 Aug 2020 23:16:20
User entered 'None (1)'	System	31 Aug 2020 23:16:20

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:16', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd139887b-8bd8-426e-8e3b-791126db88bd'	System	31 Aug 2020 23:16:20
User entered '31 Aug 2020 19:16'	System	31 Aug 2020 23:16:20

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 7'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a221de-5b25-4109-a57f-96bdfdf65ff8'	System	01 Sep 2020 23:30:49
User entered 'None (1)'	System	01 Sep 2020 23:30:49

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a221de-5b25-4109-a57f-96bdfdf65ff8'	System	01 Sep 2020 23:30:49
User entered 'No (N)'	System	01 Sep 2020 23:30:49

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:38', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a221de-5b25-4109-a57f-96bdfdf65ff8'	System	01 Sep 2020 23:30:49
User entered 'No (N)'	System	01 Sep 2020 23:30:49



US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:42', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a221de-5b25-4109-a57f-96bdfdf65ff8'	System	01 Sep 2020 23:30:49
User entered 'None (1)'	System	01 Sep 2020 23:30:49

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a221de-5b25-4109-a57f-96bdfdf65ff8'	System	01 Sep 2020 23:30:49
User entered '01 Sep 2020 19:30'	System	01 Sep 2020 23:30:49

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:23', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:28', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'None (0)'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered 'No (N)'	System	26 Aug 2020 15:56:42

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T11:56:38', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'e3522d51-7e42-4c04-9ccd-25c6ea376fac'	System	26 Aug 2020 15:56:42
User entered '26 Aug 2020 11:56'	System	26 Aug 2020 15:56:42

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 11:55'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:42:23



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:01', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:08', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:15', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:20', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'None (0)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:28', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered 'No (N)'	System	27 Aug 2020 00:01:40

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-26T20:01:32', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fd0f0238-feec-4be9-80ee-83f11612d61d'	System	27 Aug 2020 00:01:40
User entered '26 Aug 2020 20:01'	System	27 Aug 2020 00:01:40



**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '26 Aug 2020 15:20'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 2'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:28', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:36', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:42', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'None (0)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:55', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered 'No (N)'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-27T19:41:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '0b4faec1-3af8-437a-ad15-51f7f128f828'	System	27 Aug 2020 23:42:04
User entered '27 Aug 2020 19:41'	System	27 Aug 2020 23:42:04

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 3'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:42:23



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 4'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:50', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:54', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:01:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:02:00', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'None (0)'	System	29 Aug 2020 23:02:14

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:02:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered 'No (N)'	System	29 Aug 2020 23:02:14



**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-29T19:02:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '76798673-5e16-4672-80a2-cfdf7bdea438'	System	29 Aug 2020 23:02:14
User entered '29 Aug 2020 19:02'	System	29 Aug 2020 23:02:14

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 5'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:37', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba'	System	30 Aug 2020 23:56:17
User entered 'None (0)'	System	30 Aug 2020 23:56:17

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba' User entered 'None (0)'	System	30 Aug 2020 23:56:17

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba' User entered 'None (0)'	System	30 Aug 2020 23:56:17

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba' User entered 'None (0)'	System	30 Aug 2020 23:56:17



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:55', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba' User entered 'None (0)'	System	30 Aug 2020 23:56:17

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:55:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba' User entered 'None (0)'	System	30 Aug 2020 23:56:17

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:56:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba'	System	30 Aug 2020 23:56:17
User entered 'No (N)'	System	30 Aug 2020 23:56:17

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-30T19:56:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '36a01d3c-87dd-433d-9bd0-496d53f2b1ba'	System	30 Aug 2020 23:56:17
User entered '30 Aug 2020 19:56'	System	30 Aug 2020 23:56:17

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 6'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'None (0)'	System	31 Aug 2020 23:16:56



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:28', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'None (0)'	System	31 Aug 2020 23:16:56

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'None (0)'	System	31 Aug 2020 23:16:56

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630' User entered 'None (0)'	System	31 Aug 2020 23:16:56
	System	31 Aug 2020 23:16:56

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:37', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'None (0)'	System	31 Aug 2020 23:16:56

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'None (0)'	System	31 Aug 2020 23:16:56

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered 'No (N)'	System	31 Aug 2020 23:16:56

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-08-31T19:16:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '260b40e2-a661-4b94-bf97-b63706e53630'	System	31 Aug 2020 23:16:56
User entered '31 Aug 2020 19:16'	System	31 Aug 2020 23:16:56

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:42:23



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:25:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	26 Aug 2020 15:42:23
User entered 'Day 7'	System	26 Aug 2020 15:42:23

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:53', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:30:56', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:00', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:02', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25

US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:08', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'None (0)'	System	01 Sep 2020 23:31:25



US3402082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:15', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered 'No (N)'	System	01 Sep 2020 23:31:25

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6c22961000488464)', Time: '2020-09-01T19:31:19', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd4df6ec6-ecf8-431c-b8a3-3c893ad2ee5b'	System	01 Sep 2020 23:31:25
User entered '01 Sep 2020 19:31'	System	01 Sep 2020 23:31:25

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:25:39**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:42:23

**US3402082**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Sep 2020 12:03:26

**US3402082**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered '2 Sep 2020'	Traci Hull (b) (4)	03 Sep 2020 12:03:26

US3402082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	03 Sep 2020 12:03:26

US3402082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered empty.	Traci Hull (b) (4)	03 Sep 2020 12:03:26



US3402082

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Sep 2020 12:03:31

**US3402082**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	03 Sep 2020 12:03:31

**US3402082**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 15:27:57

**US3402082**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 15:27:57

US3402082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 15:27:57

US3402082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 15:27:57
	(b) (4)	

US3402082

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 15:28:01

US3402082

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	09 Sep 2020 15:28:01



**US3402082**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Sep 2020 19:34:56

**US3402082**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered '16 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	16 Sep 2020 19:34:56

**US3402082**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	16 Sep 2020 19:34:56

US3402082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered empty.	(b) (4) Tammy Kohn (b) (4)	16 Sep 2020 19:34:56
	(b) (4)	

US3402082

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Sep 2020 19:35:06

US3402082

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	16 Sep 2020 19:35:06

**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:53:59
	(b) (4)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '22 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:53:59
	(b) (4)	



US3402082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[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 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	22 Sep 2020 12:53:59

US3402082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'VISIT3'	System	22 Sep 2020 12:53:59

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Sep 2020 12:54:33

**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '22 Sep 2020'	Traci Hull (b) (4)	22 Sep 2020 12:54:33

**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '08:05'	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:54:33
	(b) (4)	

**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '22 Sep 2020 08:05'	System	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '36.8' C	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:54:33
	(b) (4)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	22 Sep 2020 12:54:33



**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:54:33
	(b) (4)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '65'	Traci Hull (b) (4)	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'bpm'	System	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '16'	(b) (4) Traci Hull (b) (4) (b) (4)	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'breaths/min'	System	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '128'	(b) (4)	
	Traci Hull (b) (4)	22 Sep 2020 12:54:33
	(b) (4)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '76'	Traci Hull (b) (4)	22 Sep 2020 12:54:33



US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'mmHg'	System	22 Sep 2020 12:54:33

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54

US3402082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54

US3402082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 12:55:00
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	22 Sep 2020 12:54:45
User entered 'No (N)'	Traci Hull (b) (4)	22 Sep 2020 12:54:45
	(b) (4)	

US3402082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered empty; reason for change New Information	Traci Hull (b) (4)	22 Sep 2020 12:55:00
User entered '22 Sep 2020'	Traci Hull (b) (4)	22 Sep 2020 12:54:45

US3402082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 12:55:14

US3402082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '22 Sep 2020'	(b) (4) Traci Hull (b) (4)	22 Sep 2020 12:55:14

**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered '08:20'	Traci Hull (b) (4)	22 Sep 2020 12:55:14



**US3402082**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered '22 Sep 2020 08:20'	System	22 Sep 2020 12:55:14

US3402082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:46:52
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Sep 2020 12:55:20

US3402082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	22 Sep 2020 12:55:20

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 64'	System	29 Jul 2020 17:52:21

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-09-30T14:15:29', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf76decf-8bb6-4f9d-9600-666d8511e23d'	System	30 Sep 2020 18:15:43
User entered 'No (N)'	System	30 Sep 2020 18:15:43

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

Have you been exposed to someone with 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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-09-30T14:15:34', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf76decf-8bb6-4f9d-9600-666d8511e23d'	System	30 Sep 2020 18:15:43
User entered 'No (N)'	System	30 Sep 2020 18:15:43

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-09-30T14:15:37', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf76decf-8bb6-4f9d-9600-666d8511e23d'	System	30 Sep 2020 18:15:43
User entered '30 Sep 2020 14:15:37'	System	30 Sep 2020 18:15:43

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 17:52:21



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 71'	System	29 Jul 2020 17:52:21

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-07T08:59:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '27462d09-5a3c-498d-968f-2cd2270ba704'	System	07 Oct 2020 13:00:08
User entered 'No (N)'	System	07 Oct 2020 13:00:08

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

Have you been exposed to someone with 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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-07T08:59:07', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '27462d09-5a3c-498d-968f-2cd2270ba704'	System	07 Oct 2020 13:00:08
User entered 'No (N)'	System	07 Oct 2020 13:00:08

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-07T08:59:57', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '27462d09-5a3c-498d-968f-2cd2270ba704' User entered '07 Oct 2020 08:59:57'	System	07 Oct 2020 13:00:08
	System	07 Oct 2020 13:00:08

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 78'	System	29 Jul 2020 17:52:21



US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-13T09:07:16', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'da362ac9-5398-4c2c-9ec9-bd6371ba5dc4'	System	13 Oct 2020 13:07:55
User entered 'No (N)'	System	13 Oct 2020 13:07:55

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

Have you been exposed to someone with 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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-13T09:07:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'da362ac9-5398-4c2c-9ec9-bd6371ba5dc4'	System	13 Oct 2020 13:07:55
User entered 'No (N)'	System	13 Oct 2020 13:07:55

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-10-13T09:07:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'da362ac9-5398-4c2c-9ec9-bd6371ba5dc4'	System	13 Oct 2020 13:07:55
User entered '13 Oct 2020 09:07:51'	System	13 Oct 2020 13:07:55

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 92'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 17:52:21



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 99'	System	29 Jul 2020 17:52:21

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-11-02T20:03:56', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '25ac04d3-0996-478b-90f9-a96b7f04355d'	System	03 Nov 2020 01:04:33
User entered 'No (N)'	System	03 Nov 2020 01:04:33

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

Have you been exposed to someone with 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 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-11-02T20:04:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '25ac04d3-0996-478b-90f9-a96b7f04355d'	System	03 Nov 2020 01:04:33
User entered 'No (N)'	System	03 Nov 2020 01:04:33

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-11-02T20:04:24', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '25ac04d3-0996-478b-90f9-a96b7f04355d'	System	03 Nov 2020 01:04:33
User entered '02 Nov 2020 20:04:24'	System	03 Nov 2020 01:04:33

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:47:20
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 106'	System	29 Jul 2020 17:52:21



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

Have you been exposed to someone with 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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**Generated On: 09 Jun 2021 17:25:39**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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**Generated On: 09 Jun 2021 17:25:39**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered 'Day 113'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

US3402082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:39

[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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Please 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 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:49:46
Data entry locked.	System	29 Jul 2020 17:52:21
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 17:52:21

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-11-23T15:20:50', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd195ef8e-d014-4b12-b86e-cd5936d7e878'	System	23 Nov 2020 20:21:49
User entered 'No (N)'	System	23 Nov 2020 20:21:49

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-11-23T15:21:27', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd195ef8e-d014-4b12-b86e-cd5936d7e878'	System	23 Nov 2020 20:21:49
User entered 'No (N)'	System	23 Nov 2020 20:21:49

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-11-23T15:21:44', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd195ef8e-d014-4b12-b86e-cd5936d7e878'	System	23 Nov 2020 20:21:49
User entered '23 Nov 2020 15:21:44'	System	23 Nov 2020 20:21:49

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-11-30T15:57:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6d173223-b8e3-4542-88f8-c2be2ba768ed'	System	30 Nov 2020 20:57:28
User entered 'No (N)'	System	30 Nov 2020 20:57:28

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-11-30T15:57:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6d173223-b8e3-4542-88f8-c2be2ba768ed'	System	30 Nov 2020 20:57:28
User entered 'No (N)'	System	30 Nov 2020 20:57:28



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-11-30T15:57:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '6d173223-b8e3-4542-88f8-c2be2ba768ed' User entered '30 Nov 2020 15:57:25'	System	30 Nov 2020 20:57:28
	System	30 Nov 2020 20:57:28

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-12-07T07:59:30', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'aa556235-98bc-4ada-bb46-24598af3a919'	System	07 Dec 2020 13:00:06
User entered 'No (N)'	System	07 Dec 2020 13:00:06

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-12-07T07:59:49', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'aa556235-98bc-4ada-bb46-24598af3a919'	System	07 Dec 2020 13:00:06
User entered 'No (N)'	System	07 Dec 2020 13:00:06

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-12-07T08:00:00', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'aa556235-98bc-4ada-bb46-24598af3a919'	System	07 Dec 2020 13:00:06
User entered '07 Dec 2020 08:00:00'	System	07 Dec 2020 13:00:06

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-12-14T09:57:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf87770f-f895-4b7f-818b-0d2953d9a67d'	System	14 Dec 2020 14:58:13
User entered 'No (N)'	System	14 Dec 2020 14:58:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-12-14T09:57:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf87770f-f895-4b7f-818b-0d2953d9a67d'	System	14 Dec 2020 14:58:13
User entered 'No (N)'	System	14 Dec 2020 14:58:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-12-14T09:58:07', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'cf87770f-f895-4b7f-818b-0d2953d9a67d'	System	14 Dec 2020 14:58:13
User entered '14 Dec 2020 09:58:07'	System	14 Dec 2020 14:58:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-12-21T12:22:02', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd68b8356-401a-4720-81cc-57a1ebac0944'	System	21 Dec 2020 17:22:32
User entered 'No (N)'	System	21 Dec 2020 17:22:32

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-12-21T12:22:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd68b8356-401a-4720-81cc-57a1ebac0944'	System	21 Dec 2020 17:22:32
User entered 'No (N)'	System	21 Dec 2020 17:22:32

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-12-21T12:22:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd68b8356-401a-4720-81cc-57a1ebac0944'	System	21 Dec 2020 17:22:32
User entered '21 Dec 2020 12:22:25'	System	21 Dec 2020 17:22:32

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2020-12-29T09:18:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '88f03026-cc7a-4946-bb89-c21fac94d7bc'	System	29 Dec 2020 14:18:31
User entered 'No (N)'	System	29 Dec 2020 14:18:31

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2020-12-29T09:18:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '88f03026-cc7a-4946-bb89-c21fac94d7bc'	System	29 Dec 2020 14:18:31
User entered 'No (N)'	System	29 Dec 2020 14:18:31



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2020-12-29T09:18:23', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '88f03026-cc7a-4946-bb89-c21fac94d7bc'	System	29 Dec 2020 14:18:31
User entered '29 Dec 2020 09:18:23'	System	29 Dec 2020 14:18:31

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-01-04T11:40:44', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '9dccf3c7-35b9-4dae-9f61-b4600aae568f'	System	04 Jan 2021 16:40:58
User entered 'No (N)'	System	04 Jan 2021 16:40:58

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-01-04T11:40:48', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '9dccf3c7-35b9-4dae-9f61-b4600aae568f'	System	04 Jan 2021 16:40:58
User entered 'No (N)'	System	04 Jan 2021 16:40:58

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-01-04T11:40:54', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '9dccf3c7-35b9-4dae-9f61-b4600aae568f' User entered '04 Jan 2021 11:40:54'	System	04 Jan 2021 16:40:58
	System	04 Jan 2021 16:40:58

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-01-11T11:43:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '4c9933c4-fe46-4d67-9976-931cbeffa519'	System	11 Jan 2021 16:44:08
User entered 'No (N)'	System	11 Jan 2021 16:44:08

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-01-11T11:43:58', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '4c9933c4-fe46-4d67-9976-931cbeffa519'	System	11 Jan 2021 16:44:08
User entered 'No (N)'	System	11 Jan 2021 16:44:08

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-01-11T11:44:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '4c9933c4-fe46-4d67-9976-931cbeffa519'	System	11 Jan 2021 16:44:08
User entered '11 Jan 2021 11:44:03'	System	11 Jan 2021 16:44:08

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-01-18T14:27:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f8ef1e15-6b1d-4f25-b92d-ef60ffd8344a'	System	18 Jan 2021 19:27:23
User entered 'No (N)'	System	18 Jan 2021 19:27:23

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-01-18T14:27:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f8ef1e15-6b1d-4f25-b92d-ef60ffd8344a'	System	18 Jan 2021 19:27:23
User entered 'No (N)'	System	18 Jan 2021 19:27:23

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-01-18T14:27:19', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f8ef1e15-6b1d-4f25-b92d-ef60ffd8344a'	System	18 Jan 2021 19:27:23
User entered '18 Jan 2021 14:27:19'	System	18 Jan 2021 19:27:23

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-01-25T07:55:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b7f2ec94-6061-46c6-ad43-b84bcb78da0b'	System	25 Jan 2021 12:55:58
User entered 'No (N)'	System	25 Jan 2021 12:55:58

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-01-25T07:55:45', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b7f2ec94-6061-46c6-ad43-b84bcb78da0b'	System	25 Jan 2021 12:55:58
User entered 'No (N)'	System	25 Jan 2021 12:55:58



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-01-25T07:55:54', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b7f2ec94-6061-46c6-ad43-b84bcb78da0b' User entered '25 Jan 2021 07:55:54'	System	25 Jan 2021 12:55:58
	System	25 Jan 2021 12:55:58

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-02-01T08:59:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '098dcd4d-ce77-4ab2-b1ed-589fa6ab1360'	System	01 Feb 2021 14:00:18
User entered 'No (N)'	System	01 Feb 2021 14:00:18

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-02-01T09:00:05', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '098dcd4d-ce77-4ab2-b1ed-589fa6ab1360'	System	01 Feb 2021 14:00:18
User entered 'No (N)'	System	01 Feb 2021 14:00:18

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-02-01T09:00:10', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '098dcd4d-ce77-4ab2-b1ed-589fa6ab1360'	System	01 Feb 2021 14:00:18
User entered '01 Feb 2021 09:00:10'	System	01 Feb 2021 14:00:18

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-02-08T08:53:04', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb55d011-5af7-4a3b-bd18-38eee7fe96a0'	System	08 Feb 2021 13:53:17
User entered 'No (N)'	System	08 Feb 2021 13:53:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-02-08T08:53:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb55d011-5af7-4a3b-bd18-38eee7fe96a0'	System	08 Feb 2021 13:53:17
User entered 'No (N)'	System	08 Feb 2021 13:53:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-02-08T08:53:14', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'eb55d011-5af7-4a3b-bd18-38eee7fe96a0'	System	08 Feb 2021 13:53:17
User entered '08 Feb 2021 08:53:14'	System	08 Feb 2021 13:53:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-02-15T06:55:59', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '70af9c22-deb4-4e92-86a3-60d0423e58dd'	System	15 Feb 2021 11:56:13
User entered 'No (N)'	System	15 Feb 2021 11:56:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-02-15T06:56:03', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '70af9c22-deb4-4e92-86a3-60d0423e58dd'	System	15 Feb 2021 11:56:13
User entered 'No (N)'	System	15 Feb 2021 11:56:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-02-15T06:56:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '70af9c22-deb4-4e92-86a3-60d0423e58dd'	System	15 Feb 2021 11:56:13
User entered '15 Feb 2021 06:56:09'	System	15 Feb 2021 11:56:13

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-02-22T07:55:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '2f1abf94-e5f3-4d2d-ac4b-bed27af2c561'	System	22 Feb 2021 12:55:57
User entered 'No (N)'	System	22 Feb 2021 12:55:57

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-02-22T07:55:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '2f1abf94-e5f3-4d2d-ac4b-bed27af2c561'	System	22 Feb 2021 12:55:57
User entered 'No (N)'	System	22 Feb 2021 12:55:57



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-02-22T07:55:52', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '2f1abf94-e5f3-4d2d-ac4b-bed27af2c561'	System	22 Feb 2021 12:55:57
User entered '22 Feb 2021 07:55:52'	System	22 Feb 2021 12:55:57

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-02-26T11:57:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ce0670ee-fbf0-4fb9-9b4c-d762480c4e52'	System	26 Feb 2021 16:57:47
User entered 'No (N)'	System	26 Feb 2021 16:57:47

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-02-26T11:57:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ce0670ee-fbf0-4fb9-9b4c-d762480c4e52'	System	26 Feb 2021 16:57:47
User entered 'No (N)'	System	26 Feb 2021 16:57:47

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-02-26T11:57:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ce0670ee-fbf0-4fb9-9b4c-d762480c4e52'	System	26 Feb 2021 16:57:47
User entered '26 Feb 2021 11:57:40'	System	26 Feb 2021 16:57:47

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-03-05T14:18:06', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f313e066-94ec-4bc3-987a-a42023b958df'	System	05 Mar 2021 19:18:17
User entered 'No (N)'	System	05 Mar 2021 19:18:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-03-05T14:18:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f313e066-94ec-4bc3-987a-a42023b958df'	System	05 Mar 2021 19:18:17
User entered 'No (N)'	System	05 Mar 2021 19:18:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-03-05T14:18:12', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'f313e066-94ec-4bc3-987a-a42023b958df' User entered '05 Mar 2021 14:18:12'	System	05 Mar 2021 19:18:17

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-03-19T07:53:31', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc92d532-d46f-48c6-ac0a-13c14c4a106d'	System	19 Mar 2021 11:54:01
User entered 'No (N)'	System	19 Mar 2021 11:54:01

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-03-19T07:53:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc92d532-d46f-48c6-ac0a-13c14c4a106d'	System	19 Mar 2021 11:54:01
User entered 'No (N)'	System	19 Mar 2021 11:54:01

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-03-19T07:53:57', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fc92d532-d46f-48c6-ac0a-13c14c4a106d' User entered '19 Mar 2021 07:53:57'	System	19 Mar 2021 11:54:01
	System	19 Mar 2021 11:54:01

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:49:46

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-03-26T12:58:57', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fa64dd66-3c6c-4497-bea2-91e718ab1261'	System	26 Mar 2021 16:59:14
User entered 'No (N)'	System	26 Mar 2021 16:59:14

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-03-26T12:59:02', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fa64dd66-3c6c-4497-bea2-91e718ab1261'	System	26 Mar 2021 16:59:14
User entered 'No (N)'	System	26 Mar 2021 16:59:14

**US3402082**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-03-26T12:59:09', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'fa64dd66-3c6c-4497-bea2-91e718ab1261'	System	26 Mar 2021 16:59:14
User entered '26 Mar 2021 12:59:09'	System	26 Mar 2021 16:59:14

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-04-03T09:04:39', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ba8ef385-4f15-4bcc-aebc-7649acdc70b3'	System	03 Apr 2021 13:04:54
User entered 'No (N)'	System	03 Apr 2021 13:04:54



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-04-03T09:04:43', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ba8ef385-4f15-4bcc-aebc-7649acdc70b3'	System	03 Apr 2021 13:04:54
User entered 'No (N)'	System	03 Apr 2021 13:04:54

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-04-03T09:04:47', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'ba8ef385-4f15-4bcc-aebc-7649acdc70b3'	System	03 Apr 2021 13:04:54
User entered '03 Apr 2021 09:04:47'	System	03 Apr 2021 13:04:54

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-04-09T19:56:02', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1992bcfc-f70c-4db6-a528-dd527eb6af4d'	System	09 Apr 2021 23:56:28
User entered 'No (N)'	System	09 Apr 2021 23:56:28

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-04-09T19:56:07', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1992bcfc-f70c-4db6-a528-dd527eb6af4d'	System	09 Apr 2021 23:56:28
User entered 'No (N)'	System	09 Apr 2021 23:56:28

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-04-09T19:56:25', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '1992bcfc-f70c-4db6-a528-dd527eb6af4d'	System	09 Apr 2021 23:56:28
User entered '09 Apr 2021 19:56:25'	System	09 Apr 2021 23:56:28



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-04-16T14:55:41', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '033aa6af-721b-44c4-9d2d-99357a511f53'	System	16 Apr 2021 18:55:57
User entered 'No (N)'	System	16 Apr 2021 18:55:57

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-04-16T14:55:46', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '033aa6af-721b-44c4-9d2d-99357a511f53'	System	16 Apr 2021 18:55:57
User entered 'No (N)'	System	16 Apr 2021 18:55:57

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-04-16T14:55:51', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: '033aa6af-721b-44c4-9d2d-99357a511f53'	System	16 Apr 2021 18:55:57
User entered '16 Apr 2021 14:55:51'	System	16 Apr 2021 18:55:57

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-04-23T08:15:22', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a4a9844b-1ef5-422c-9601-df3a43607a8d'	System	23 Apr 2021 12:15:41
User entered 'No (N)'	System	23 Apr 2021 12:15:41

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-04-23T08:15:28', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a4a9844b-1ef5-422c-9601-df3a43607a8d'	System	23 Apr 2021 12:15:41
User entered 'No (N)'	System	23 Apr 2021 12:15:41

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-04-23T08:15:35', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'a4a9844b-1ef5-422c-9601-df3a43607a8d' User entered '23 Apr 2021 08:15:35'	System	23 Apr 2021 12:15:41
	System	23 Apr 2021 12:15:41

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[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 (a2fb434d5bb3466e)', Time: '2021-04-30T08:35:37', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b8872b15-b1de-41e5-a9ff-8d078d2a4b7a'	System	30 Apr 2021 12:35:48
User entered 'No (N)'	System	30 Apr 2021 12:35:48



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

Have you been exposed to someone with 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 (a2fb434d5bb3466e)', Time: '2021-04-30T08:35:40', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b8872b15-b1de-41e5-a9ff-8d078d2a4b7a'	System	30 Apr 2021 12:35:48
User entered 'No (N)'	System	30 Apr 2021 12:35:48

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-04-30T08:35:44', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'b8872b15-b1de-41e5-a9ff-8d078d2a4b7a' User entered '30 Apr 2021 08:35:44'	System	30 Apr 2021 12:35:48
	System	30 Apr 2021 12:35:48

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:49:46



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:49:46



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:49:46



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:49:46



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:49:46



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:49:46

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:49:46



**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:49:46

**US3402082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:25:39**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:49:46
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:49:46

US3402082

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:25:39**

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 06:26:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-03-10T11:45:15', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd5e803fe-1d06-403d-94c2-6f75d8d400bc'	System	10 Mar 2021 16:45:48
User entered 'No (N)'	System	10 Mar 2021 16:45:48

**US3402082**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:26:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2fb434d5bb3466e)', Time: '2021-03-10T11:45:26', User OID: 'PatientReportedOutcome (US3402082)', ODM File OID: 'd5e803fe-1d06-403d-94c2-6f75d8d400bc'	System	10 Mar 2021 16:45:48
User entered '10 Mar 2021 11:45:26'	System	10 Mar 2021 16:45:48

**US3402082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:13:18
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	20 Oct 2020 11:46:25

**US3402082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:13:18
User entered '19 Oct 2020'	Tammy Kohn (b) (4)	20 Oct 2020 11:46:25

**US3402082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:13:18
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	20 Oct 2020 11:46:25

US3402082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:13:18
User entered empty.	Tammy Kohn (b) (4)	20 Oct 2020 11:46:25



US3402082

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:13:18
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	20 Oct 2020 11:46:28

**US3402082**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:32:54
User entered 'I'	System	20 Oct 2020 11:46:28

**US3402082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Dec 2020 13:26:54

**US3402082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '23 Nov 2020'	Jennifer Molstead (b) (4)	11 Dec 2020 13:26:54

**US3402082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Molstead (b) (4)	11 Dec 2020 13:26:54

US3402082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	11 Dec 2020 13:26:54

US3402082

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Dec 2020 13:27:00

**US3402082**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User entered 'I'	System	11 Dec 2020 13:27:00



**US3402082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Dec 2020 20:08:53

**US3402082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '22 Dec 2020'	Traci Hull (b) (4)	22 Dec 2020 20:08:53

**US3402082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	22 Dec 2020 20:08:53

US3402082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	22 Dec 2020 20:08:53
	(b) (4)	

US3402082

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4)	22 Dec 2020 20:08:58
	Traci Hull (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User entered 'I'	System	22 Dec 2020 20:08:58

**US3402082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:07:20

US3402082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:34:49
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CORRECT AS IS' (Site from System).	Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:07:36
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Feb 2021 15:07:20
User entered '14 Jan 2021'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:07:20



**US3402082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:07:20

US3402082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:07:20

US3402082

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:07:42

**US3402082**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:20:53
User entered 'I'	System	09 Feb 2021 15:07:42

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4)	09 Feb 2021 15:07:54
	Traci Hull (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '9 Feb 2021'	(b) (4)	09 Feb 2021 15:07:54
	Traci Hull (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[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 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	09 Feb 2021 15:07:54

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'VISIT4'	System	09 Feb 2021 15:07:54



US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
Comment added 'VITALS NOT REQUIRED'.	Traci Hull (b) (4)	31 Mar 2021 15:31:24
User entered 'No (N)'	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31



**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31
	(b) (4)	

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Jennifer Molstead (b) (4)	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered empty.	System	30 Mar 2021 23:24:31

US3402082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36



**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:25:39**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Feb 2021 15:08:04

US3402082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '9 Feb 2021'	(b) (4)	09 Feb 2021 15:08:04
	Traci Hull (b) (4)	
	(b) (4)	

US3402082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	17 Mar 2021 19:13:12

US3402082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '9 Feb 2021'	(b) (4) Tammy Kohn (b) (4)	17 Mar 2021 19:13:12

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '08:47'	Tammy Kohn (b) (4)	17 Mar 2021 19:13:12

**US3402082**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered '9 Feb 2021 08:47'	System	17 Mar 2021 19:13:12

US3402082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Feb 2021 15:08:08



US3402082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:26:36
User entered 'I'	System	09 Feb 2021 15:08:08

**US3402082**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	23 Mar 2021 20:17:47

**US3402082**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:25:39**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '23 Mar 2021'	Traci Hull (b) (4)	23 Mar 2021 20:17:47

US3402082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	23 Mar 2021 20:17:47

US3402082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:39

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered empty.	Traci Hull (b) (4)	23 Mar 2021 20:17:47

US3402082

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	23 Mar 2021 20:17:52

**US3402082**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:58:19
User entered 'I'	System	23 Mar 2021 20:17:52

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:51:34
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:23:57



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:51:34
User entered '12:30'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:23:57

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:25:39**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:19
User entered '16 Feb 2021 12:30'	System	16 Feb 2021 18:23:57

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:51:34
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:23:57

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:25:39**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:51:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:23:57

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 1 (Day 1)'	(b) (4) Traci Hull (b) (4)	16 Feb 2021 18:25:16

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '13 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16



**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:25:39**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:16

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 2 (Day 2)'	(b) (4) Traci Hull (b) (4)	16 Feb 2021 18:25:55

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '14 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	16 Feb 2021 18:25:55

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:25:55



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 3 (Day 3)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '15 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31



**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:26:31

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 4 (Day 4)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:25:39**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '37.2' C	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:06

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 5 (Day 5)'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '17 Feb 2021'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:25:39**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 13:17:10

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 6 (Day 6)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '18 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	19 Feb 2021 13:21:21

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:21



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 7 (Day 7)'	(b) (4) Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '19 Feb 2021'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '97.1' F	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:25:39**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54



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Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Feb 2021 12:58:54

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 20 (Day 20)'	(b) (4) Tammy Kohn (b) (4)	22 Feb 2021 20:18:24

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '20 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:25:39**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98.8' F	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 21 (Day 21)'	(b) (4) Tammy Kohn (b) (4)	22 Feb 2021 20:18:24

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '21 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '98.1' F	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4)	22 Feb 2021 20:18:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



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Folder: Covid-19 Assessment 16 Feb 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 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

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Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:18:24

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'Day 22 (Day 22)'	(b) (4) Tammy Kohn (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '22 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '0'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '96'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 17:25:39**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User entered '%'	System	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered '97.3' F	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4)	22 Feb 2021 20:20:26
	(b) (4)	

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:30
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 20:20:26



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:25:39**

[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 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:25:39**

[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 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[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 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27



US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:39
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:27

US3402082

Folder: Covid-19 Assessment 16 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:39

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:30
User entered '0'	System	16 Feb 2021 18:24:27

**US3402082**

**Folder: Covid-19 Assessment 16 Feb 2021**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:25:39**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 22:13:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:53:44
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:24:06

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:50:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 07:48:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'CORRECTED DATES SHOULD BE 18, 20, 22 FEB 2021' (Site from DM).	Tammy Kohn (b) (4)	08 Mar 2021 18:52:07
	(b) (4)	
User entered '18 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:39
	(b) (4)	
User entered '16 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:04
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20,22FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:06:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:05:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:05:09

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:39

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Feb 2021'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44



**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:39
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered '20 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:39
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:39
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered '22 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Mar 2021 18:51:39
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:59:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:58:36
Query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' answered with 'updated answer to NA' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:28:50
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:28:37
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:28:37
User opened query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:21:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44



**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:25:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:00:43
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:59:50
Query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' answered with 'UPDATED TO NA ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:05
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:28:55
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:28:55
User opened query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:21:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:25:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:02:20
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:01:56
Query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' answered with 'UPDATED TO NA ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:13
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:11
User opened query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:22:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:25:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

US3402082

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:25:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:03:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:02:53
Query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' answered with 'UPDATED TO NA ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:22
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:19
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 12:29:19
User opened query 'Per ETRTR: Please consider updating answer to "NA (Covid-19 Negative)" per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:22:08
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44



**US3402082**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:23
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Feb 2021 13:21:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:20
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:49:20
User entered '16 Feb 2021'	Traci Hull (b) (4)	16 Feb 2021 18:27:44
	(b) (4)	

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[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 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:20
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:27:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered 'SICKD1'	System	16 Feb 2021 18:27:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '12:37'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32



**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered '16 Feb 2021 12:37'	System	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered missing code ND - Not Done.	Traci Hull (b) (4)	16 Feb 2021 18:28:32
DataPoint set to visible.	(b) (4) System	16 Feb 2021 18:27:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered missing code ND - Not Done.	Traci Hull (b) (4)	16 Feb 2021 18:28:32
DataPoint set to visible.	(b) (4) System	16 Feb 2021 18:27:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '37.2' C	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	20 Apr 2021 15:49:50
User entered 'Oral (Oral)'	Traci Hull (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '85'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered 'bpm'	System	16 Feb 2021 18:28:32



**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '14'	Traci Hull (b) (4)	16 Feb 2021 18:28:32
	(b) (4)	

US3402082

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered 'breaths/min'	System	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '120'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:32

US3402082

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered 'mmHg'	System	16 Feb 2021 18:28:32

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:49:50
User entered '84'	Traci Hull (b) (4)	16 Feb 2021 18:28:32
	(b) (4)	

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:25:39**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User entered 'mmHg'	System	16 Feb 2021 18:28:32

US3402082

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25

US3402082

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25



US3402082

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:44

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:25:39**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:49:55
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:44

US3402082

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:25:39

[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 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:03
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:59

**US3402082**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:25:39**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:50:03
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 18:28:59

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Jan 2021 13:45:56
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '28 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	29 Jan 2021 13:46:07
	(b) (4)	
User entered '06 Jan 2021'	Tammy Kohn (b) (4)	29 Jan 2021 13:45:56
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:39

[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 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	29 Jan 2021 13:45:56
	(b) (4)	

**US3402082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:25:39**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 13:45:56



US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '06 Jan 2021'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[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 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	08 Apr 2021 16:30:35
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:47:01

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:47:09
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	08 Apr 2021 16:31:00
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Traci Hull (b) (4)	08 Apr 2021 16:30:35
	(b) (4)	
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:22:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:47:01

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '28 Jan 2021'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	



US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:25:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:01
	(b) (4)	

**US3402082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:39**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User entered empty.	System	29 Jan 2021 13:47:01

**US3402082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:25:39**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User entered empty.	System	29 Jan 2021 13:47:01

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:16
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '28 Jan 2021'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:16
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '13:44'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:16
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User entered '28 Jan 2021 13:44'	System	29 Jan 2021 13:47:16

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:28
	(b) (4)	



US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '28 Jan 2021'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:28
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
	(b) (4)	
User entered '13:45'	Tammy Kohn (b) (4)	29 Jan 2021 13:47:28
	(b) (4)	

US3402082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:32:02
User entered '28 Jan 2021 13:45'	System	29 Jan 2021 13:47:28

US3402082

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
User closed query 'Per ETRTR: AE is required for medical condition or alternate diagnosis other than COVID-19 that triggered the Illness Visit performed on 16Feb21. Please add AE as required per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 18:44:16
Query 'Per ETRTR: AE is required for medical condition or alternate diagnosis other than COVID-19 that triggered the Illness Visit performed on 16Feb21. Please add AE as required per CCG's, thanks.' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	21 Apr 2021 16:13:03
User opened query 'Per ETRTR: AE is required for medical condition or alternate diagnosis other than COVID-19 that triggered the Illness Visit performed on 16Feb21. Please add AE as required per CCG's, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:06:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:47:22
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:32:19
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	03 Feb 2021 19:37:25
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 17:51:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:54:02
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:29
User entered	System	04 Feb 2021 12:51:25
'USA-US059-2021-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 12:51:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:54:04
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Coordination and balance disturbances, PT: Balance disorder, LLT: Unsteadiness - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 10:37:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 10:37:47
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Coordination and balance disturbances, PT: Balance disorder, LLT: Balance disorder - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:56:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 18:56:49
Data point term sent to Coder	System	03 Feb 2021 19:44:45
User entered 'Unstable balance'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
	(b) (4)	

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:06
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:08
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05



**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:09
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:11
User entered '1 Feb 2021'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:13
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:54:14
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 22:15:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 22:15:48
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 22:15:48
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 19:44:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:54:16
User entered '3 Feb 2021'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
	(b) (4)	

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:56:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 19:44:05



**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:56:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:56:41
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:56:43
User entered '0'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
	(b) (4)	

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:56:44
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:56:46
User entered 'I'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
	(b) (4)	

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:56:48
User entered '1 Feb 2021'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:06
User entered '3 Feb 2021'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:09
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05



**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:10
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

US3402082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:12
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:17
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:19
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:21
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:23
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:58:31
User entered '0'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'PV Query: It was reported that the subject's use of ventlin HFA was solely used as treatment in the hospital. Please add this treatment medication to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If not adding, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:06:22
Query 'PV Query: It was reported that the subject's use of ventlin HFA was solely used as treatment in the hospital. Please add this treatment medication to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If not adding, please clarify.' answered with 'SUBJECT HAS BEEN ON VENTILIN HFA FOR SOME TIME ACCORDING TO MEDICAL RECORDS. ADDED TO MH' (Site from Safety). DataPoint Verified.	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:29:15
	(b) (4), (b) (6)	16 Apr 2021 15:58:34
User opened query 'PV Query: It was reported that the subject's use of ventlin HFA was solely used as treatment in the hospital. Please add this treatment medication to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If not adding, please clarify.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:28:42
User closed query 'Per CDM re-query: Response noted; Please add the Con med and con proc once the medical records are available. Please leave the query open till an update made else respond to clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 04:59:00
Query 'Per CDM re-query: Response noted; Please add the Con med and con proc once the medical records are available. Please leave the query open till an update made else respond to clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 14:44:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:16:12
User opened query 'Per CDM re-query: Response noted; Please add the Con med and con proc once the medical records are available. Please leave the query open till an update made else respond to clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:16:10
Query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' answered with 'Awaiting medical records' (Site from DM).	Jennifer Molstead (b) (4)	17 Feb 2021 18:53:08
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:05:22
User entered 'I'	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:36
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:16:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' answered with 'Awaiting medical records' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	17 Feb 2021 18:53:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:05:02
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:58:39
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Feb 2021 19:44:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User closed query 'Per DM CLR: Narrative = FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:27:07
Query 'Per DM CLR: Narrative = FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'AE ADDED FOR THE FALL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:29:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:58:42
User opened query 'Per DM CLR: Narrative = FELL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:03:31
User closed query 'PV Query: can you confirm whether or not the report of chornic lumbar radiculopathy should be considered as medical history?' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:48:33
User closed query 'PV Query: can you confirm whether or not the subject's use of ventlin HFA was prior to event onset, or if it was solely used as treatment in the hospital' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:48:30
Query 'PV Query: can you confirm whether or not the report of chornic lumbar radiculopathy should be considered as medical history?' answered with 'CHRONIC LUMBAR RADICULOPATHY SHOULD BE IN SUBJECTS MH. UPDATED ALL INFORMATION' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	22 Mar 2021 14:26:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS WEAKENED LEFT LOWER EXTREMITY, LOST HIS BALANCE ON THE ICE AND FELL. DUE TO WEAKENED EXTREMITY AND ICY CONDITION SUBJECT WAS UNABLE TO STAND UP. HE ENDED UP GOING TO THE HOSPITAL TO MAKE SURE EVERYTHING WAS OKAY. THEY ENDED UP ADMITTING HIM AND DOING A FULL WORK UP BEING THAT THE SUBJECT IS A DIABETIC. SUBJECT DID HAVE CBC, CMP, UA, TROPONIN LEVEL, MRI BRAIN, AND CHEST XRAY, ALL OF WHICH WERE NORMAL. SARSCOV2 TEST NEGATIVE' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	22 Mar 2021 14:26:14
Query 'PV Query: can you confirm whether or not the subject's use of ventlin HFA was prior to event onset, or if it was solely used as treatment in the hospital' answered with 'SOLELY USED AS TREATMENT IN THE HOSPITAL. ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	22 Mar 2021 14:01:58
User opened query 'PV Query: can you confirm whether or not the report of chornic lumbar radiculopathy should be considered as medical history?' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 12:56:45
User opened query 'PV Query: can you confirm whether or not the subject's use of ventlin HFA was prior to event onset, or if it was solely used as treatment in the hospital' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 12:56:36
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:32:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:32:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 17:32:25
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Mar 2021 15:02:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Mar 2021 14:48:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Mar 2021 14:47:55



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS WEAKENED LEFT LOWER EXTREMITY, LOST HIS BALANCE ON THE ICE AND FELL. DUE TO WEAKENED EXTREMITY AND ICY CONDITION SUBJECT WAS UNABLE TO STAND UP. HE ENDED UP GOING TO THE HOSPITAL TO MAKE SURE EVERYTHING WAS OKAY. THEY ENDED UP ADMITTING HIM AND DOING A FULL WORK UP BEING THAT THE SUBJECT IS A DIABETIC. SUBJECT DID HAVE CBC, CMP, UA, TROPONIN LEVEL, MRI BRAIN, AND CHEST XRAY, ALL OF WHICH WERE NORMAL. Subject was not tested for COVID' reason for change: New Information	Jennifer Molstead (b) (4)	14 Mar 2021 14:47:49
User entered 'SUBJECT HAS WEAKENED LEFT LOWER EXTREMITY, LOST HIS BALANCE ON THE ICE AND FELL. DUE TO WEAKENED EXTREMITY AND ICY CONDITION SUBJECT WAS UNABLE TO STAND UP. HE ENDED UP GOING TO THE HOSPITAL TO MAKE SURE EVERYTHING WAS OKAY. THEY ENDED UP ADMITTING HIM AND DOING A FULL WORK UP BEING THAT THE SUBJECT IS A DIABETIC. Subject did have CBC, CMP, UA, Troponin level, MRI Brain, and Chest xray, all of which were normal.' reason for change: New Information	Jennifer Molstead (b) (4)	14 Mar 2021 14:47:19
User entered 'SUBJECT HAS WEAKENED LEFT LOWER EXTREMITY, LOST HIS BALANCE ON THE ICE AND FELL. DUE TO WEAKENED EXTREMITY AND ICY CONDITION SUBJECT WAS UNABLE TO STAND UP. HE ENDED UP GOING TO THE HOSPITAL TO MAKE SURE EVERYTHING WAS OKAY. THEY ENDED UP ADMITTING HIM AND DOING A FULL WORK UP BEING THAT THE SUBJECT IS A DIABETIC, AWATING MEDICAL RECORDS FOR PROCEDURES AND MEDICATIONS.' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Feb 2021 15:05:17

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:28:59
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:28:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:28:48
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so ' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:28:48
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	17 Feb 2021 18:53:22
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so ' answered with 'Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	17 Feb 2021 18:53:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:39

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 21:28:52
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 21:28:39
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 21:28:26
User entered 'Subject has weaakend left lower extremity, lost his balance on the ice and fell. due to weakened extremity and icy condition subject was unable to stand up. He ended up going to the hospital to make sure everything was okay. They ended up admitting him and doing a full work up being that the subject is a diabetic,	Jennifer Molstead (b) (4)	03 Feb 2021 19:44:05
Awating medical records for procedures and medications.'		

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 19:44:05

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Gastrointestinal upset - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:35:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:35:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 01:05:38
Data point term sent to Coder	System	21 Apr 2021 16:09:05
User entered 'Gastro Intestinal Upset'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:25:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:05:44
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '13 Feb 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User entered empty.	System	21 Apr 2021 16:08:37

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 01:06:22
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 16:08:47
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	21 Apr 2021 16:08:47
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 16:08:37
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	21 Apr 2021 16:08:37

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '15 Feb 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User entered empty.	System	21 Apr 2021 16:08:37

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37



**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

US3402082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'l'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	22 Apr 2021 01:06:22
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 16:08:37

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User entered '0'	System	21 Apr 2021 16:08:37



**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25
User entered '0'	System	21 Apr 2021 16:08:37

**US3402082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:25:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 19:47:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: BASAGLAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 21:48:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 21:48:40
Data point term sent to Coder	System	24 Sep 2020 18:59:25
Coding entries removed.	Tammy Kohn (b) (4)	24 Sep 2020 18:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jul 2020 20:51:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jul 2020 20:51:27
Data point term sent to Coder	System	29 Jul 2020 19:49:33
User entered 'BASAGLER INSULIN'	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '30'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'IU (IU)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:48:54
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:44:13
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 18:58:53
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 18:58:45
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 04:44:06
User entered 'Intramuscular (INTRAMUSCULAR)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:48:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:39:27
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)	29 Jul 2020 19:49:06
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	29 Jul 2020 19:48:54
User entered 'UN UNK 2006'	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:48:54

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:48:54



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:48:54
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:48:54

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:48:54

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:48:54

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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) (b) (4) (b) (4)	29 Jul 2020 20:42:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:23
Data point term sent to Coder	System	29 Jul 2020 19:54:38
User entered 'ZOLPIDEM'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:53:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:53:43
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'INSOMNIA'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:53:43



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '5'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:53:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:53:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'as needed (PRN)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:53:43
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:39:33
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)	29 Jul 2020 20:01:41
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	29 Jul 2020 19:53:43
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:53:43
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:53:43
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Tarin Gordon (b) (4)	29 Jul 2020 19:53:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:53:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:53:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:53:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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.	(b) (4) (b) (4) Coder Import (b) (4)	29 Jul 2020 20:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:21
Data point term sent to Coder	System	29 Jul 2020 19:54:38
User entered 'METFORMIN'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:54:24



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:54:24
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '1000'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:54:24

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'twice daily (BID)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:54:24

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	(b) (4)	29 Jul 2020 19:54:24
	Tarin Gordon (b) (4)	
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:39:37
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)	29 Jul 2020 20:01:36
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	29 Jul 2020 19:54:24
User entered 'UN UNK 2006'	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:54:24

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:54:24
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:54:24
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Jul 2020 19:54:24

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:54:24



**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:54:24

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jul 2020 20:42:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jul 2020 20:42:26
Data point term sent to Coder	System	29 Jul 2020 19:55:40
User entered 'GABAPENTIN'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor) and location (e.g. arms, legs, etc.). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 08:57:07
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor) and location (e.g. arms, legs, etc.). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'BILATERAL LEGS ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 18:57:13
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor) and location (e.g. arms, legs, etc.). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:17:27
User entered 'NEUROPATHY'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:55:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '600'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:55:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'three times daily (TID)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:55:09



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:55:09
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:39:43
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.'	Tarin Gordon (b) (4)	29 Jul 2020 20:01:13
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	29 Jul 2020 19:55:09
User entered 'UN UNK 2006'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:55:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:55:09
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:55:09
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:09
	(b) (4)	



**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Jul 2020 19:55:09

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:55:09

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:55:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROXIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jul 2020 17:23:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jul 2020 17:23:10
Data point term sent to Coder	System	29 Jul 2020 19:56:41
User entered 'HYDROXINE'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:55:48
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'ANXIETY'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '50'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:55:48
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:39:48
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)	29 Jul 2020 20:01:07
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	29 Jul 2020 19:55:48
User entered 'UN Dec 2019'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:55:48
	Tarin Gordon (b) (4)	
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:55:48
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:55:48
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:55:48

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:55:48

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 19:55:48

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jul 2020 20:42:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jul 2020 20:42:28
Data point term sent to Coder	System	29 Jul 2020 19:56:41
User entered 'OMEPRAZOLE'	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:56:34
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '40'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 18:39:54
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)	29 Jul 2020 20:01:02
User entered 'UN UNK 2005'	(b) (4)	
	System	29 Jul 2020 19:56:34
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:56:34
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:56:34
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:56:34

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:56:34

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:56:34

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:32
Data point term sent to Coder	System	29 Jul 2020 19:59:42
User entered 'LISINOPRIL'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:58:50



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'HYPERTENSION'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:58:50

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '10'	(b) (4)	29 Jul 2020 19:58:50
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:58:50

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:58:50
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:58:50
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:40:00
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)	29 Jul 2020 20:00:56
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	29 Jul 2020 19:58:50
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:58:50

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:58:50
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 19:58:50
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:58:50
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:58:50

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:58:50



**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:58:50

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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)	29 Jul 2020 20:42:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:32
Data point term sent to Coder	System	29 Jul 2020 19:59:42
User entered 'ATORVASTATIN'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:59:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '80'	(b) (4)	29 Jul 2020 19:59:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:59:31
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	29 Jul 2020 19:59:31



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:59:31
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	(b) (4)	29 Jul 2020 19:59:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 19:59:31
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:40:05
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)	29 Jul 2020 20:00:42
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	29 Jul 2020 19:59:31
User entered 'UN UNK 2013'	Tarin Gordon (b) (4)	29 Jul 2020 19:59:31
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 19:59:31
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	29 Jul 2020 19:59:31
	Tarin Gordon (b) (4)	
	(b) (4)	



**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:59:31

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 19:59:31

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 19:59:31

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jul 2020 20:42:32
Data point term sent to Coder	System	29 Jul 2020 20:00:43
User entered 'ESCITALOPRAM'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 20:00:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'ANXIETY'	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '20'	(b) (4)	29 Jul 2020 20:00:09
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
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 18:40:11
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)	29 Jul 2020 20:00:18
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	29 Jul 2020 20:00:09
User entered 'UN Dec 2019'	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Tarin Gordon (b) (4)	29 Jul 2020 20:00:09

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 20:00:09
	Tarin Gordon (b) (4)	
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	29 Jul 2020 20:00:09
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	29 Jul 2020 20:00:09
	(b) (4)	

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 20:00:09

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 20:00:09

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 20:00:09

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 12:15:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:52:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:52:26
Data point term sent to Coder	System	28 Feb 2021 16:51:43
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	28 Feb 2021 16:50:58
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'Subjects condition did not worsen.' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	28 Feb 2021 16:50:46
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 09:12:51

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:11:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:11:47
Data point term sent to Coder	System	09 Feb 2021 15:10:48
User entered 'VICTOZA'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 08:05:12
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Mar 2021 13:09:57
User entered '1.2' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Mar 2021 13:09:27
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 13:36:23
User entered '1.8'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 12:15:22
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	28 Feb 2021 16:51:06
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	28 Feb 2021 16:50:58
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 09:12:41
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '20 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	09 Feb 2021 15:09:59
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	09 Feb 2021 15:09:59

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 15:09:59

US3402082

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 15:09:59

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 15:09:59



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 01:38:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 01:38:56
Data point term sent to Coder	System	14 Mar 2021 14:40:46
User entered 'Fluticasone'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Unstable Balance'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:02:57
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	06 Apr 2021 14:14:29
User entered '50/100' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	06 Apr 2021 14:13:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:42:51
User entered '0.05/10'	Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'UG/MG' reason for change: Data Entry Error	Traci Hull (b) (4)	06 Apr 2021 14:13:56
User entered 'mg/ug'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	Jennifer Molstead (b) (4) 14 Mar 2021 14:40:25
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '02 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:40:25

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Mar 2021 14:40:25



**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Mar 2021 14:40:25

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Mar 2021 14:40:25

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 06:24:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 06:24:03
Data point term sent to Coder	System	14 Mar 2021 14:41:47
User entered 'Folic Acid'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:25:39**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Unstable Balance'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'I'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '02 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:25:39**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:41:08

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Mar 2021 14:41:08

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Mar 2021 14:41:08

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Mar 2021 14:41:08

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE 5% - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 06:22:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:22:53
Data point term sent to Coder	System	14 Mar 2021 14:44:49
User entered 'dextrose 5%'	Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'unstable balance'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '1000'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'mL (mL)'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'continuos'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '02 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '0'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30
	(b) (4)	



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '04 Feb 2021'	Jennifer Molstead (b) (4)	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'No (N)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 14:44:30

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
User entered empty.	System	14 Mar 2021 14:44:30

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
User entered empty.	System	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:29
User entered empty.	System	14 Mar 2021 14:44:30

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: VENTOLIN HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 11:51:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 11:51:04
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 11:20:30
User entered 'VENTOLIN HFA'	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISORDER'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered '90'	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'ug (ug)'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered empty.	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered empty.	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43



US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'UN UNK 2006'	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered '0'	Jennifer Molstead (b) (4)	15 Apr 2021 11:19:43
	(b) (4)	

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

US3402082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:57:19
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Apr 2021 11:19:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:25:39**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 11:19:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 11:19:43

**US3402082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:25:39**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 11:19:43



US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:25:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:32
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:42:27
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	11 Mar 2021 14:56:17
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 17:51:08

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '1 Feb 2021'	Jennifer Molstead (b) (4)	11 Mar 2021 14:56:45

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Complete Blood COut'	Jennifer Molstead (b) (4)	11 Mar 2021 14:56:45

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	11 Mar 2021 14:56:45

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	11 Mar 2021 14:56:45

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '1 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 14:57:17
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Complete Metabolic Profile'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 14:57:17

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 14:57:17
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 14:57:17
	(b) (4)	

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '01 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 14:57:57
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Troponin'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 14:57:57

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 14:57:57

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 14:57:57
	(b) (4)	

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '1 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 15:15:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'CT Head without Contrast'	Jennifer Molstead (b) (4)	11 Mar 2021 15:15:06

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:15:06



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:15:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '01 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 15:36:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Chest xray 1 view'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:36:52

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:36:52

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:22:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:36:52
	(b) (4)	

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '03 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 15:38:19
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:38:19

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:38:19



US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:38:19
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '03 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 15:39:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Complete metabolic profile'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:39:06

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:39:06

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:39:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '01 Feb 2021'	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:39:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'urinalysis'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:39:35

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	11 Mar 2021 15:39:35



US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	11 Mar 2021 15:39:35
	(b) (4)	

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '02 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	11 Mar 2021 15:41:09

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'US Carotid duplex bilateral'	Jennifer Molstead (b) (4)	11 Mar 2021 15:41:09

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	11 Mar 2021 15:41:09

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	Jennifer Molstead (b) (4)	11 Mar 2021 15:41:09

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:25:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered '03 Feb 2021'	(b) (4) Jennifer Molstead (b) (4)	14 Mar 2021 15:02:59
	(b) (4)	

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:25:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'MRI BRain'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 15:02:59

US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:25:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	14 Mar 2021 15:02:59



US3402082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:25:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:23:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:57:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:23:46
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	14 Mar 2021 15:02:59
	(b) (4)	

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
User entered '04/Feb/2021 07:51'	System	04 Feb 2021 12:51:53

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:25:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
User entered '24/Feb/2021 11:46'	System	24 Feb 2021 16:46:03

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:25:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 17:32:48
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:46:03

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
User entered '15/Mar/2021 12:33'	System	15 Mar 2021 17:33:01

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:25:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:48:06
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 17:33:01

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
User entered '23/Mar/2021 10:48'	System	23 Mar 2021 14:48:03



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:25:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:48:06
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 14:48:03

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'USA-US059-2021-MRNA-1273-P301000008'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Yes (Y)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25



US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'No (N)'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Frank'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Eder'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '1290 Upper Front Street'	System	04 Feb 2021 12:51:25

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:39

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'Binghamton'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered 'NY'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:51:48
User entered '13901'	System	04 Feb 2021 12:51:25

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 15:59:08
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:45:51
User entered 'US'	System	04 Feb 2021 12:51:53



**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:25:39**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Apr 2021 14:06:56
User entered '4'	System	23 Mar 2021 14:48:03
User entered '3'	System	15 Mar 2021 17:33:01
User entered '2'	System	24 Feb 2021 16:46:03
User entered '1'	System	04 Feb 2021 12:51:53

**US3402082**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:25:39**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered '20/Apr/2021 10:06'	(b) (4) System	20 Apr 2021 14:06:56

US3402082

Folder: SAE USA-US059-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:25:39

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:33:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:06:56