

US3802034 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 12 Aug 2021 17:46:30

All time stamps listed in this document are displayed in GMT

US3802034

Form: Participant Creation

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

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Participant ID

US3802034

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

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US3802034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

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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) 10 Sep 2020 20:53:03

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Condition	FREQUENT UTI
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) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3802034

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

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 (7)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Condition	ACID REFLUX
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Condition	HEADACHE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Jan 2021 15:27:02

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Condition	GENERAL MUSCLE PAIN
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 13:40
Height (xxx.x)	156 cm
Weight (xxx.x)	166 lb
BMI (xxx.x)	31.00532 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 20:53:03

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 10 Sep 2020 20:53:02

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Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Sep 2020 20:53:03

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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**

CARE PROVIDER

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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) 10 Sep 2020 20:53:03

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Jan 2021 15:27:02

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What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 188024

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Height	156 cm
Weight	166 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Height	156 cm
Weight	166 lb
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)	25 AUG 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 13:40
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Height	156 cm
Weight	166 lb
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)	25 AUG 2020
Time of assessment (00:00-23:59)	14:52 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 14:52
Temperature (xxx.x)	97 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 14:11 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 14:11

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) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

13:55 (24 HR)

Collection date and time (derived)

25 AUG 2020 13:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:48	25 AUG 2020 13:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 15:00

PC Open Date & Time

25 AUG 2020 14:31

PC Close Date & Time

25 AUG 2020 17:01

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	25 AUG 2020 20:19
PC Open Date & Time	25 AUG 2020 17:56
PC Close Date & Time	26 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 20:44

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**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

98.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 22:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 AUG 2020 07:58

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 22:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:44

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:56

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 15:02

PC Open Date & Time

25 AUG 2020 14:31

PC Close Date & Time

25 AUG 2020 17:01

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**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

25 AUG 2020 20:19

PC Open Date & Time

25 AUG 2020 17:56

PC Close Date & Time

26 AUG 2020 11:59



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 20:45

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**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

27 AUG 2020 22:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**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 07:58

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**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

29 AUG 2020 22:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 6
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	30 AUG 2020 21:44
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**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

31 AUG 2020 20:57

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**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 ☐

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 16:48
PC Open Date & Time	25 AUG 2020 14:31
PC Close Date & Time	25 AUG 2020 17:01



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**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 ☐

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 20:20
PC Open Date & Time	25 AUG 2020 17:56
PC Close Date & Time	26 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:45
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:10
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 07:59
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:42
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:45
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**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 ☒

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:57
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3802034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 20:53:03

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:05
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:06
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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.*



US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 09:35

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

US3802034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

21 SEP 2020 09:05

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:19	21 SEP 2020 09:19
Nasopharyngeal Swab 2	No		

US3802034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**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

96.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 21 SEP 2020 10:11

PC Open Date & Time 21 SEP 2020 09:55

PC Close Date & Time 21 SEP 2020 12:25

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**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 96.7 °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	21 SEP 2020 21:47
PC Open Date & Time	21 SEP 2020 13:20
PC Close Date & Time	22 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 SEP 2020 21:17

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 21:26

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 21:56

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**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

97.6 °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

25 SEP 2020 20:44

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

26 SEP 2020 20:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**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.

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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

27 SEP 2020 21:51

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**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

21 SEP 2020 10:11

PC Open Date & Time

21 SEP 2020 09:55

PC Close Date & Time

21 SEP 2020 12:25

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**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

21 SEP 2020 21:47

PC Open Date & Time

21 SEP 2020 13:20

PC Close Date & Time

22 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**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

22 SEP 2020 21:18

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:26

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**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

24 SEP 2020 21:56

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**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

25 SEP 2020 20:44

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 20:32

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 21:51

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**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 ☐

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:12
PC Open Date & Time	21 SEP 2020 09:55
PC Close Date & Time	21 SEP 2020 12:25

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**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 ☐

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 21:48
PC Open Date & Time	21 SEP 2020 13:20
PC Close Date & Time	22 SEP 2020 11:59



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**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 ☒

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:19
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

98 of 3181

EAB) (1725)

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

100 of 3181

EAB) (1725)

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 21:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:45
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:33
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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 ☒

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:52
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3802034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3802034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:59
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	60 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)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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.*

US3802034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	13:06 (24 HR)
Collection date and time (derived)	19 OCT 2020 13:06

US3802034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<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	25 OCT 2020 06:07:08
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59



US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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 <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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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 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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 19:41:55
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 12:24:30
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 17:59:44

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 06:59:31
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59



US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 06:19:02
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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	27 DEC 2020 18:31:29
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 DEC 2020 10:54:20
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 17:59:32
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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

25 JAN 2021 03:52:35

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 16:44:48
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59



US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 13:24:14
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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15 FEB 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 10:01:34
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 17:00:38
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 15:37:38

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 MAR 2021 23:59



US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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

18 MAR 2021 06:43:42

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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

29 MAR 2021 06:05:49

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<b>TIMEPOINT</b>	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	04 APR 2021 06:35:57
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 21:00:40

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 07:28:43
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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

22 APR 2021 06:10:40

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

<b>TIMEPOINT</b>	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 <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 MAY 2021 12:32:06
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐  
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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐  
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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59
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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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13 SEP 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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°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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59
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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐  
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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐ 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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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°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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

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08 AUG 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐  
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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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"/>



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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17 OCT 2022 23:59

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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**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 ☐



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

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

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

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[Patient Cloud Close Date & Time](#)

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31 OCT 2022 23:59

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US3802034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 17:46:30

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		08 MAR 2021 15:37:52

US3802034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:44:52

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

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.*

US3802034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

09:22 (24 HR)

Collection date and time (derived)

17 MAR 2021 09:22



US3802034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 15:11:03

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 15:11:03

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3802034**

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

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

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*

**US3802034**

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

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

Date of Contact	5 NOV 2020
Time of Contact	11:02
Date and Time of Contact (derived)	5 NOV 2020 11:02
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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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Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		



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Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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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Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 2020	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	100 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Symptom Day

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

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	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (12)

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Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (12)

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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Symptom Day

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

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	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020	
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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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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

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Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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

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Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020
------	-------------

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

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

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 14:42:54

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 NOV 2020
------	-------------

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

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

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

Temperature	97.5 F
-------------	--------

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

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

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

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

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Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (19)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (19)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (20)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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"/>

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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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Form: Symptom Log (21)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (21)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (22)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (24)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (24)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (25)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (25)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (25)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (26)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Form: Symptom Log (26)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (26)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Form: Symptom Log (26)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

Date	01 DEC 2020
------	-------------

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

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

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

Temperature	97.2 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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 05 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Symptom Day

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

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

Date	03 DEC 2020
------	-------------

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

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

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

Temperature	97.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

	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"/>

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Date of Visit	5 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	5 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

If Yes, provide:

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

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

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
Heart Rate \_\_\_\_\_

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

If Yes, provide:

Start Date 13 NOV 2020  
End Date 13 NOV 2020  
Oxygen Saturation 90 %

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

If Yes, provide:

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

Did the subject have Respiratory failure? Yes ☐ No ☒

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

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

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

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:42:54

Generated On: 12 Aug 2021 17:46:30

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

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

Start Date

End Date

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Mar 2021 12:30:43

Generated On: 12 Aug 2021 17:46:30

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	7 NOV 2020
Day 5	Yes	9 NOV 2020
Day 7	Yes	11 NOV 2020
Day 9	Yes	13 NOV 2020
Day 14	Yes	18 NOV 2020
Day 21	Yes	25 NOV 2020
Day 28	Yes	4 DEC 2020



US3802034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	11:04 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 11:04
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFARED
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3802034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 10 Nov 2020 10:24:41

Generated On: 12 Aug 2021 17:46:30

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

5 NOV 2020

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 15:27:00

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Jan 2021 15:27:00

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 DEC 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 09:05
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFARED
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 15:27:00

Generated On: 12 Aug 2021 17:46:30

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.*

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Jan 2021 15:27:00

Generated On: 12 Aug 2021 17:46:30

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

4 DEC 2020



US3802034

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

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

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

Visit date (dd MMM yyyy)	6 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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US3802034

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 18:33:33

Generated On: 12 Aug 2021 17:46:30

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

US3802034

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Height	155.2 cm
Weight	159 lb
BMI (xxx.x)	30.00482

US3802034

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Height	155.2 cm
Weight	159 lb
BMI (xxx.x)	30.00482
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)	6 JAN 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 12:15
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Height	155.2 cm
Weight	159 lb
BMI (xxx.x)	30.00482
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)	6 JAN 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 13:25
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

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

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

6 JAN 2021

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

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US3802034

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

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 12:55

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3802034

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	12:34 (24 HR)
Collection date and time (derived)	6 JAN 2021 12:34



US3802034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	12:37
Collection Date and Time (derived)	6 JAN 2021 12:37

US3802034

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

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:27:02

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3802034

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	OLD29

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

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)	3 FEB 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 11:40
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

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)	3 FEB 2021
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 12:29
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3802034

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

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.*



US3802034

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 11:52 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 11:52

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

US3802034

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802034

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802034

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

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.*

US3802034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Mar 2021 15:55:04

Generated On: 12 Aug 2021 17:46:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

09:22 (24 HR)

Collection date and time (derived)

17 MAR 2021 09:22



US3802034

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 10 Nov 2020 10:24:40

Generated On: 12 Aug 2021 17:46:30

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Mar 2021 16:27:37

Generated On: 12 Aug 2021 17:46:30

AEID	USA-US098-2020-MRNA-1273-P30 1000003
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	5 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Mar 2021 16:27:37

Generated On: 12 Aug 2021 17:46:30

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	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Mar 2021 16:27:37

Generated On: 12 Aug 2021 17:46:30

AEID

Adverse event

TOOTH INFECTION

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Mar 2021 16:27:37

Generated On: 12 Aug 2021 17:46:30

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

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

---

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

Yes ☒

No ☐

---

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

---

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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 2000	
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 (3)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication	PEPCID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACID REFLUX
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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 2000	
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"/>

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE AND GENERALIZED  
MUSCLE PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INFLUENZA  
INFECTION

Dose per administration UNK

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 (8)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication TOOTH INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication TOOTH INFECTION

Dose per administration UNK

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

If dose unit is Other, specify PACK

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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US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication CONGESTION, SORE THROAT,  
AND COUGH AS RELATED TO  
COVID 19 INFECTION

Dose per administration UNK

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE DUE TO COVID-19

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)		8 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENT HEART DISEASE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication BODY ACHES, INJECTION SITE  
PAIN, FEVER

Dose per administration UNK

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 (15)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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)	6 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

Name of Medication ASMANEX

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration UNKNOWN

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 (16)

Data signed: (b) (4) 12 Mar 2021 14:50:28

Generated On: 12 Aug 2021 17:46:30

	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) _____		
Start date completely unknown		True
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3802034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 12:25:24

Generated On: 12 Aug 2021 17:46:30

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3802034

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

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

US3802034

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 10 Sep 2020 20:53:02

Generated On: 12 Aug 2021 17:46:30

Date of study discontinuation/completion ( <i>dd MMM yyyy</i> )	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death ( <i>dd MMM yyyy</i> )	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 17:58:28

Generated On: 12 Aug 2021 17:46:30

SAEID	USA-US098-2020-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 17:58:28

Generated On: 12 Aug 2021 17:46:30

SAEID	USA-US098-2020-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/NOV/2020 17:14
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

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Mar 2021 17:58:28

Generated On: 12 Aug 2021 17:46:30

SAEID	USA-US098-2020-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/NOV/2020 20:29
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



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Mar 2021 17:58:28

Generated On: 12 Aug 2021 17:46:30

SAEID	USA-US098-2020-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/JAN/2021 12:47
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

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Mar 2021 17:58:28

Generated On: 12 Aug 2021 17:46:30

SAEID	USA-US098-2020-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	(b) (6)
Investigator's Last Name	(b) (6)
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/MAR/2021 13:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3802034 (Prod: UPMC University Center)

**US3802034**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 17:46:30**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'US3802034'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:34:51

US3802034

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 17:35:04
	(b) (4)	

US3802034

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:34:52

US3802034

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:04

**US3802034**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'SCRN'	System	25 Aug 2020 17:35:04



US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:34:53

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '70'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'YEARS'	System	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '70'	System	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Female (F)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 17:35:24

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'I'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24



US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

US3802034

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 17:46:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

**US3802034**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 17:46:30**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:24

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37



**US3802034**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 17:46:30**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Aug 2020'	System	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2020'	System	25 Aug 2020 17:35:37

**US3802034**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 17:46:30**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Amendment 3 (3)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:37

US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:34:52



US3802034

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 17:46:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'I'	System	25 Aug 2020 17:35:41

US3802034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 17:46:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:35:41

US3802034

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 17:46:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:10

US3802034

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 17:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:39:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:39:34
Data point term sent to Coder	System	25 Aug 2020 18:38:30
User entered 'Right foot fracture'	Lalicia Roman (b) (4)	25 Aug 2020 18:38:27
	(b) (4)	

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2005'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:38:27

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:38:27

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:38:27

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2005'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:38:27



**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:38:27

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Jan 2005'	System	25 Aug 2020 18:38:27

US3802034

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 17:46:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2005'	System	25 Aug 2020 18:38:27

**US3802034**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Jan 2005'	System	25 Aug 2020 18:38:27

US3802034

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 17:46:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2005'	System	25 Aug 2020 18:38:27

US3802034

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Recurrent UTI - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Aug 2020 06:38:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Aug 2020 06:38:43
Data point term sent to Coder	System	25 Aug 2020 18:39:34
User entered 'Frequent UTI'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2010'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:39:19

US3802034

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:39:19



**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:39:19
	(b) (4)	

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Jan 2010'	System	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2010'	System	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	25 Aug 2020 18:39:19

**US3802034**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	25 Aug 2020 18:39:19

US3802034

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Aug 2020 18:44:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:44:44
Data point term sent to Coder	System	25 Aug 2020 18:43:46
User entered 'Asthma'	Lalicia Roman (b) (4)	25 Aug 2020 18:43:42
	(b) (4)	



**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2000'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:43:42

US3802034

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Jan 2000'	System	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2000'	System	25 Aug 2020 18:43:42

**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	25 Aug 2020 18:43:42



**US3802034**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	25 Aug 2020 18:43:42

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Oct 2020 15:15:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:15:37
Data point term sent to Coder	(b) (4)	07 Oct 2020 14:19:16
User entered 'post menopausal'	System Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered 'I'	Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered '0'	Melissa Andrasko (b) (4)	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	07 Oct 2020 14:18:29



**US3802034**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 17:46:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	07 Oct 2020 14:18:29

**US3802034**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	07 Oct 2020 14:18:29

US3802034

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 19:31:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:31:31
Data point term sent to Coder	System	19 Oct 2020 19:30:51
User entered 'Hypertension'	Melissa Andrasko (b) (4) (b) (4) (b) (4)	19 Oct 2020 19:30:34

US3802034

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	13 Nov 2020 20:00:54
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Jennifer Nagg (b) (4)	13 Nov 2020 20:00:54
User signature succeeded.	(b) (4)	
	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	19 Oct 2020 19:30:54
User entered 'UN UNK 2020' reason for change:	Melissa Andrasko (b) (4)	19 Oct 2020 19:30:54
Data Entry Error		
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).		
	System	19 Oct 2020 19:30:34
User entered ' 2010' (non-conformant).	Melissa Andrasko (b) (4)	19 Oct 2020 19:30:34

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Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:30:34

US3802034

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 17:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:30:34

**US3802034**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 17:46:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:30:34



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Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 17:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:30:34

**US3802034**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'Jan 2010'	System	13 Nov 2020 20:00:54
User entered 'Jan 2020'	System	19 Oct 2020 19:30:54
User entered empty.	System	19 Oct 2020 19:30:34

**US3802034**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '2010'	System	13 Nov 2020 20:00:54
User entered '2020'	System	19 Oct 2020 19:30:54
User entered empty.	System	19 Oct 2020 19:30:34

**US3802034**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:30:34

**US3802034**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:30:34

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
DataPoint Verified.		18 Nov 2020 21:12:44
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
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: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 19:36:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:36:33
Data point term sent to Coder	System	19 Oct 2020 19:35:03
User entered 'acid reflux'	Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:32:13
User closed query 'No Year stated in source , please confirm ' (Site from CRA).		23 Nov 2020 17:32:08
Query 'No Year stated in source , please confirm ' answered with 'Updated' (Site from CRA).	Lalicia Roman (b) (4)	23 Nov 2020 13:45:50
Signature has been broken.	(b) (4) Lalicia Roman (b) (4)	23 Nov 2020 13:45:38
User entered empty; reason for change Data Entry Error	(b) (4) Lalicia Roman (b) (4)	23 Nov 2020 13:45:38
User opened query 'No Year stated in source , please confirm ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:13:30
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'UN UNK 2018'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:32:10
DataPoint Un-verified.	Lalicia Roman (b) (4)	23 Nov 2020 13:45:38
Signature has been broken.	(b) (4) Lalicia Roman (b) (4)	23 Nov 2020 13:45:38
User entered '1' reason for change: Data Entry Error	(b) (4) Lalicia Roman (b) (4)	23 Nov 2020 13:45:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:12:57
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19



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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
DataPoint Verified.		18 Nov 2020 21:13:00
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19

US3802034

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
DataPoint Verified.		18 Nov 2020 21:13:01
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4)	
	Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
DataPoint Verified.		18 Nov 2020 21:13:03
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:34:19

**US3802034**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	23 Nov 2020 13:45:38
User entered 'Jan 2018'	System	19 Oct 2020 19:34:19

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Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 17:46:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	23 Nov 2020 13:45:38
User entered '2018'	System	19 Oct 2020 19:34:19

**US3802034**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:34:19

**US3802034**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:34:19

US3802034

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of MUSCLE PAIN. 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).		19 Nov 2020 10:22:52
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 09). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 10:59:50
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:25:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:25:17
Data point term sent to Coder	System	29 Oct 2020 15:11:43
Query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of MUSCLE PAIN. 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 'participant did not disclose this information ' (Site from DM).	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:15
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 09). ' answered with 'updated ' (Site from DM).	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:03
User entered 'HEADACHE' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:10:57
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of MUSCLE PAIN. 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)	28 Oct 2020 17:14:21

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Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 09). ' (Site from DM). Data point term sent to Coder User entered 'headache/muscle pain'	(b) (4), (b) (6)	28 Oct 2020 17:12:49
	System	19 Oct 2020 19:38:10
	Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

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Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

US3802034

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'I'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

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Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered 'Yes (Y)'	Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

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Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

US3802034

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:38:03

US3802034

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:38:03

**US3802034**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 17:46:30**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:38:03



**US3802034**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:38:03

US3802034

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 17:46:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	19 Oct 2020 19:38:03

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:25:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:25:17
Data point term sent to Coder	System	29 Oct 2020 15:11:44
User entered 'general muscle pain'	Emily Carney (b) (4)	29 Oct 2020 15:11:33
	(b) (4)	

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:33

**US3802034**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 17:46:30**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'I'	(b) (4) Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:33

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:33

**US3802034**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 17:46:30**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:33

**US3802034**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 17:46:30**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Emily Carney (b) (4) (b) (4)	29 Oct 2020 15:11:33



US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	29 Oct 2020 15:11:33

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	29 Oct 2020 15:11:33

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	29 Oct 2020 15:11:33

US3802034

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 17:46:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered empty.	System	29 Oct 2020 15:11:33

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '13:40'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

**US3802034**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered '25 Aug 2020 13:40'	System	25 Aug 2020 17:41:09



US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	25 Aug 2020 17:41:34
User entered '156' cm reason for change: Data Entry Error	System	25 Aug 2020 17:41:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Dominic Kramer (b) (4)	25 Aug 2020 17:41:34
User entered '156c' (non-conformant).	(b) (4)	25 Aug 2020 17:41:09
DataPoint set to visible.	System	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '166' lb	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09
DataPoint set to visible.	(b) (4) System	25 Aug 2020 17:35:41

**US3802034**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
Amendment Manager: User entered '31.00532'	System	17 Sep 2020 00:02:10
User entered '31.0'	System	25 Aug 2020 17:41:34
User entered empty.	System	25 Aug 2020 17:41:09
DataPoint set to visible.	System	25 Aug 2020 17:35:41

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'kg/m2'	System	25 Aug 2020 17:41:34
User entered empty.	System	25 Aug 2020 17:41:09
DataPoint set to visible.	System	25 Aug 2020 17:35:41

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '98' F	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Other (Other)'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Infrared'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '77'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09



**US3802034**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'bpm'	System	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '18'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'breaths/min'	System	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered '135'	Dominic Kramer (b) (4) (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'mmHg'	System	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '86'	(b) (4) Dominic Kramer (b) (4)	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User entered 'mmHg'	System	25 Aug 2020 17:41:09

US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14



US3802034

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14

US3802034

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:14:28
	(b) (4)	

US3802034

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:14:28
	(b) (4)	

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		29 Oct 2020 09:30:55
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	07 Oct 2020 14:18:41
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:07:43
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59



**US3802034**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 17:46:30**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

**US3802034**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 17:46:30**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'I'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:14:59

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:16:41
	(b) (4)	

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41



US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'care provider'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41



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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

**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 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'I'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:16:41
	(b) (4)	

US3802034

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 17:46:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:50:14
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:16:41



US3802034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:17:07

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:17:07

US3802034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:17:07

US3802034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'VISIT1'	System	25 Aug 2020 18:17:07

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:40:07

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '188024'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:40:07

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 17:40:07

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:40:28



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:40:28

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:40:28

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:40:28

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 17:40:28

US3802034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 17:46:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 22:04:19
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'data entered' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 21:18:00
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 21:17:52
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:51:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:52:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:52:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '156' cm	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '166' lb	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '156' cm	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44



US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '166' lb	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Pre-Dose (PREDOSE)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44
	(b) (4)	

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '13:40'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '25 Aug 2020 13:40'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '98' F	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'Other (Other)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '77'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'bpm'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '18'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'breaths/min'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '135'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '86'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44



US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '156' cm	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '166' lb	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Post-Dose (POSTDOSE)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '14:52'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '25 Aug 2020 14:52'	System	25 Aug 2020 19:14:44



US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '97' F	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '88'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'bpm'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '18'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'breaths/min'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '136'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44



US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '88'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	25 Aug 2020 19:14:44

US3802034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:17:28

US3802034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:17:28

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:18:38



US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '14:11'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:18:38
	(b) (4)	

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '25 Aug 2020 14:11'	System	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'ONCE'	System	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 18:18:38

US3802034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:29



US3802034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:29
	(b) (4)	

US3802034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '13:55'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:29
	(b) (4)	

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '25 Aug 2020 13:55'	System	25 Aug 2020 18:20:29

US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25 Aug 2020'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:45
	(b) (4)	

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:20:45

US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:45

US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '13:48'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:45
	(b) (4)	

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '25 Aug 2020 13:48'	System	25 Aug 2020 18:20:45



US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:20:45

US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:45
	(b) (4)	

US3802034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 18:20:45
	(b) (4)	

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered empty.	System	25 Aug 2020 18:20:45

US3802034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 18:20:52

**US3802034**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	25 Aug 2020 18:20:52

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T14:59:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b8dd599e-5669-4731-be35-75aaa6cacef2'	System	25 Aug 2020 19:00:08
User entered 'Yes (Y)'	System	25 Aug 2020 19:00:08



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T14:59:40', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b8dd599e-5669-4731-be35-75aaa6cacef2' User entered '97.0'	System	25 Aug 2020 19:00:08
	System	25 Aug 2020 19:00:08

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T14:59:49', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b8dd599e-5669-4731-be35-75aaa6cacef2'	System	25 Aug 2020 19:00:08
User entered 'No (N)'	System	25 Aug 2020 19:00:08

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:00:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b8dd599e-5669-4731-be35-75aaa6cacef2'	System	25 Aug 2020 19:00:08
User entered '25 Aug 2020 15:00'	System	25 Aug 2020 19:00:08

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 14:31'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:18:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '04a6eda7-a56c-4f3a-9aca-55bc8202ee68' User entered 'Yes (Y)'	System	26 Aug 2020 00:19:26
	System	26 Aug 2020 00:19:26

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '04a6eda7-a56c-4f3a-9aca-55bc8202ee68' User entered '98.4'	System	26 Aug 2020 00:19:26
	System	26 Aug 2020 00:19:26



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '04a6eda7-a56c-4f3a-9aca-55bc8202ee68'	System	26 Aug 2020 00:19:26
User entered 'No (N)'	System	26 Aug 2020 00:19:26

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '04a6eda7-a56c-4f3a-9aca-55bc8202ee68' User entered '25 Aug 2020 20:19'	System	26 Aug 2020 00:19:26
	System	26 Aug 2020 00:19:26

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:56'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 2'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3fd8cb4f-8c62-47a8-9b73-242a20db2ab2'	System	27 Aug 2020 00:44:40
User entered 'Yes (Y)'	System	27 Aug 2020 00:44:40

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:26', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3fd8cb4f-8c62-47a8-9b73-242a20db2ab2' User entered '97.4'	System	27 Aug 2020 00:44:40
	System	27 Aug 2020 00:44:40

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3fd8cb4f-8c62-47a8-9b73-242a20db2ab2'	System	27 Aug 2020 00:44:40
User entered 'No (N)'	System	27 Aug 2020 00:44:40



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:38', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3fd8cb4f-8c62-47a8-9b73-242a20db2ab2'	System	27 Aug 2020 00:44:40
User entered '26 Aug 2020 20:44'	System	27 Aug 2020 00:44:40

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 3'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:07:49', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743' User entered 'Yes (Y)'	System	28 Aug 2020 02:08:41
	System	28 Aug 2020 02:08:41

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743' User entered '98.0'	System	28 Aug 2020 02:08:41
	System	28 Aug 2020 02:08:41

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743'	System	28 Aug 2020 02:08:41
User entered 'Yes (Y)'	System	28 Aug 2020 02:08:41

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient contacted and Advil taken ' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 14:37:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:17', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743'	Emily Dougherty (b) (4)	01 Sep 2020 21:07:27
User entered '1'	System	28 Aug 2020 02:08:41
	System	28 Aug 2020 02:08:41
	System	28 Aug 2020 02:08:41



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:17', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743' User entered '0'	System	28 Aug 2020 02:08:41
	System	28 Aug 2020 02:08:41

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:35', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eeba91c7-4b78-4eb9-8d4e-0e89c060c743'	System	28 Aug 2020 02:08:41
User entered '27 Aug 2020 22:08'	System	28 Aug 2020 02:08:41

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 4'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:28', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '80f1b655-e835-4c67-9794-95daa87156a7'	System	29 Aug 2020 11:58:43
User entered 'Yes (Y)'	System	29 Aug 2020 11:58:43

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '80f1b655-e835-4c67-9794-95daa87156a7' User entered '97.7'	System	29 Aug 2020 11:58:43
	System	29 Aug 2020 11:58:43

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:37', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '80f1b655-e835-4c67-9794-95daa87156a7'	System	29 Aug 2020 11:58:43
User entered 'No (N)'	System	29 Aug 2020 11:58:43



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:42', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '80f1b655-e835-4c67-9794-95daa87156a7'	System	29 Aug 2020 11:58:43
User entered '29 Aug 2020 07:58'	System	29 Aug 2020 11:58:43

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 5'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:40:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0ea1c0aa-9306-40d4-a3e8-1e29eafa91c7' User entered 'Yes (Y)'	System	30 Aug 2020 02:41:16
	System	30 Aug 2020 02:41:16

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0ea1c0aa-9306-40d4-a3e8-1e29eafa91c7' User entered '96.6'	System	30 Aug 2020 02:41:16
	System	30 Aug 2020 02:41:16

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0ea1c0aa-9306-40d4-a3e8-1e29eafa91c7'	System	30 Aug 2020 02:41:16
User entered 'No (N)'	System	30 Aug 2020 02:41:16

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0ea1c0aa-9306-40d4-a3e8-1e29eafa91c7' User entered '29 Aug 2020 22:41'	System	30 Aug 2020 02:41:16
	System	30 Aug 2020 02:41:16



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 6'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:43:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '38f087a4-1ec3-4674-96ba-2c93934a6522' User entered 'Yes (Y)'	System	31 Aug 2020 01:44:15
	System	31 Aug 2020 01:44:15

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '38f087a4-1ec3-4674-96ba-2c93934a6522' User entered '97.4'	System	31 Aug 2020 01:44:15
	System	31 Aug 2020 01:44:15

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '38f087a4-1ec3-4674-96ba-2c93934a6522'	System	31 Aug 2020 01:44:15
User entered 'No (N)'	System	31 Aug 2020 01:44:15

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '38f087a4-1ec3-4674-96ba-2c93934a6522'	System	31 Aug 2020 01:44:15
User entered '30 Aug 2020 21:44'	System	31 Aug 2020 01:44:15

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 7'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:56:37', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '178a9cf2-d2cc-4d70-ab72-a63cd7dc7e8a' User entered 'Yes (Y)'	System	01 Sep 2020 00:56:54
	System	01 Sep 2020 00:56:54

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:56:42', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '178a9cf2-d2cc-4d70-ab72-a63cd7dc7e8a' User entered '97.8'	System	01 Sep 2020 00:56:54
	System	01 Sep 2020 00:56:54

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:56:46', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '178a9cf2-d2cc-4d70-ab72-a63cd7dc7e8a'	System	01 Sep 2020 00:56:54
User entered 'No (N)'	System	01 Sep 2020 00:56:54

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:56:52', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '178a9cf2-d2cc-4d70-ab72-a63cd7dc7e8a'	System	01 Sep 2020 00:56:54
User entered '31 Aug 2020 20:56'	System	01 Sep 2020 00:56:54

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:01:23', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7f84cdce-7ccc-4fc0-b68c-287e62b5b624'	System	25 Aug 2020 19:02:04
User entered 'None (1)'	System	25 Aug 2020 19:02:04

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:01:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7f84cdce-7ccc-4fc0-b68c-287e62b5b624'	System	25 Aug 2020 19:02:04
User entered 'No (N)'	System	25 Aug 2020 19:02:04

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:01:40', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7f84cdce-7ccc-4fc0-b68c-287e62b5b624'	System	25 Aug 2020 19:02:04
User entered 'No (N)'	System	25 Aug 2020 19:02:04

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:01:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7f84cdce-7ccc-4fc0-b68c-287e62b5b624'	System	25 Aug 2020 19:02:04
User entered 'None (1)'	System	25 Aug 2020 19:02:04

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:02:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7f84cdce-7ccc-4fc0-b68c-287e62b5b624'	System	25 Aug 2020 19:02:04
User entered '25 Aug 2020 15:02'	System	25 Aug 2020 19:02:04

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 14:31'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:36', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5efddf2f-1bcc-4940-aad7-7a9ecbe531f2'	System	26 Aug 2020 00:20:05
User entered 'None (1)'	System	26 Aug 2020 00:20:05

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5efddf2f-1bcc-4940-aad7-7a9ecbe531f2'	System	26 Aug 2020 00:20:05
User entered 'No (N)'	System	26 Aug 2020 00:20:05

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5efddf2f-1bcc-4940-aad7-7a9ecbe531f2'	System	26 Aug 2020 00:20:05
User entered 'No (N)'	System	26 Aug 2020 00:20:05

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5efddf2f-1bcc-4940-aad7-7a9ecbe531f2'	System	26 Aug 2020 00:20:05
User entered 'None (1)'	System	26 Aug 2020 00:20:05

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:19:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5efddf2f-1bcc-4940-aad7-7a9ecbe531f2'	System	26 Aug 2020 00:20:05
User entered '25 Aug 2020 20:19'	System	26 Aug 2020 00:20:05

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:56'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 2'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:46', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b1ccd7fc-9514-4b7e-84d3-5d724006c141'	System	27 Aug 2020 00:45:12
User entered 'None (1)'	System	27 Aug 2020 00:45:12

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:50', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b1ccd7fc-9514-4b7e-84d3-5d724006c141'	System	27 Aug 2020 00:45:12
User entered 'No (N)'	System	27 Aug 2020 00:45:12

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b1ccd7fc-9514-4b7e-84d3-5d724006c141' User entered 'No (N)'	System	27 Aug 2020 00:45:12
	System	27 Aug 2020 00:45:12

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:44:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b1ccd7fc-9514-4b7e-84d3-5d724006c141'	System	27 Aug 2020 00:45:12
User entered 'None (1)'	System	27 Aug 2020 00:45:12

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:10', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'b1ccd7fc-9514-4b7e-84d3-5d724006c141' User entered '26 Aug 2020 20:45'	System	27 Aug 2020 00:45:12
	System	27 Aug 2020 00:45:12

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 3'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:42', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '97d2a87c-193b-4e06-839e-34ea6f36ec2f' User entered 'None (1)'	System	28 Aug 2020 02:09:08
	System	28 Aug 2020 02:09:08

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:45', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '97d2a87c-193b-4e06-839e-34ea6f36ec2f' User entered 'No (N)'	System	28 Aug 2020 02:09:08
	System	28 Aug 2020 02:09:08

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:49', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '97d2a87c-193b-4e06-839e-34ea6f36ec2f' User entered 'No (N)'	System	28 Aug 2020 02:09:08
	System	28 Aug 2020 02:09:08

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:08:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '97d2a87c-193b-4e06-839e-34ea6f36ec2f' User entered 'None (1)'	System	28 Aug 2020 02:09:08
	System	28 Aug 2020 02:09:08

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:07', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '97d2a87c-193b-4e06-839e-34ea6f36ec2f' User entered '27 Aug 2020 22:09'	System	28 Aug 2020 02:09:08
	System	28 Aug 2020 02:09:08

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 4'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:57:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7545d22c-cf76-458f-8653-3cf8c2b5da40'	System	29 Aug 2020 11:58:20
User entered 'None (1)'	System	29 Aug 2020 11:58:20

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7545d22c-cf76-458f-8653-3cf8c2b5da40'	System	29 Aug 2020 11:58:20
User entered 'No (N)'	System	29 Aug 2020 11:58:20

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7545d22c-cf76-458f-8653-3cf8c2b5da40'	System	29 Aug 2020 11:58:20
User entered 'No (N)'	System	29 Aug 2020 11:58:20

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:08', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7545d22c-cf76-458f-8653-3cf8c2b5da40'	System	29 Aug 2020 11:58:20
User entered 'None (1)'	System	29 Aug 2020 11:58:20

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:18', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7545d22c-cf76-458f-8653-3cf8c2b5da40' User entered '29 Aug 2020 07:58'	System	29 Aug 2020 11:58:20
	System	29 Aug 2020 11:58:20

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 5'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:20', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'af7eecb8-74b7-451b-8c00-d2949e8d5d4b' User entered 'None (1)'	System	30 Aug 2020 02:41:41
	System	30 Aug 2020 02:41:41

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'af7eecb8-74b7-451b-8c00-d2949e8d5d4b' User entered 'No (N)'	System	30 Aug 2020 02:41:41
	System	30 Aug 2020 02:41:41

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:28', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'af7eecb8-74b7-451b-8c00-d2949e8d5d4b' User entered 'No (N)'	System	30 Aug 2020 02:41:41
	System	30 Aug 2020 02:41:41

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:32', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'af7eecb8-74b7-451b-8c00-d2949e8d5d4b'	System	30 Aug 2020 02:41:41
User entered 'None (1)'	System	30 Aug 2020 02:41:41

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:39', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'af7eecb8-74b7-451b-8c00-d2949e8d5d4b' User entered '29 Aug 2020 22:41'	System	30 Aug 2020 02:41:41
	System	30 Aug 2020 02:41:41

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 6'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:21', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2ac5f2df-5d93-4a3f-858f-2e14af3d7dee'	System	31 Aug 2020 01:44:38
User entered 'None (1)'	System	31 Aug 2020 01:44:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2ac5f2df-5d93-4a3f-858f-2e14af3d7dee'	System	31 Aug 2020 01:44:38
User entered 'No (N)'	System	31 Aug 2020 01:44:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:27', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2ac5f2df-5d93-4a3f-858f-2e14af3d7dee'	System	31 Aug 2020 01:44:38
User entered 'No (N)'	System	31 Aug 2020 01:44:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2ac5f2df-5d93-4a3f-858f-2e14af3d7dee'	System	31 Aug 2020 01:44:38
User entered 'None (1)'	System	31 Aug 2020 01:44:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2ac5f2df-5d93-4a3f-858f-2e14af3d7dee'	System	31 Aug 2020 01:44:38
User entered '30 Aug 2020 21:44'	System	31 Aug 2020 01:44:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 7'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:56:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e80eb365-cb68-486d-b262-611f68863c26' User entered 'None (1)'	System	01 Sep 2020 00:57:21
	System	01 Sep 2020 00:57:21

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e80eb365-cb68-486d-b262-611f68863c26' User entered 'No (N)'	System	01 Sep 2020 00:57:21
	System	01 Sep 2020 00:57:21

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:08', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e80eb365-cb68-486d-b262-611f68863c26' User entered 'No (N)'	System	01 Sep 2020 00:57:21
	System	01 Sep 2020 00:57:21

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:13', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e80eb365-cb68-486d-b262-611f68863c26'	System	01 Sep 2020 00:57:21
User entered 'None (1)'	System	01 Sep 2020 00:57:21

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e80eb365-cb68-486d-b262-611f68863c26' User entered '31 Aug 2020 20:57'	System	01 Sep 2020 00:57:21
	System	01 Sep 2020 00:57:21

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T15:12:50', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'No interference with activity (1)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:46:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'None (0)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:47:03', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'None (0)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:47:08', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'None (0)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:47:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'None (0)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:47:15', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'None (0)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:47:21', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered 'No (N)'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T16:48:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '49ab32c0-a878-4060-a0a4-ceddce21fe4b' User entered '25 Aug 2020 16:48'	System	25 Aug 2020 20:48:26
	System	25 Aug 2020 20:48:26

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 14:31'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:11', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:20', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:31', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:37', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'None (0)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:45', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered 'No (N)'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-25T20:20:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '01be6888-a354-45ac-a63c-d15ffa7b036b' User entered '25 Aug 2020 20:20'	System	26 Aug 2020 00:20:59
	System	26 Aug 2020 00:20:59

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Aug 2020 17:56'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 2'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:16', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:20', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:29', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:36', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'None (0)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered 'No (N)'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-26T20:45:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd1ea72bb-d349-4e30-b39a-c8d0cf1d54de' User entered '26 Aug 2020 20:45'	System	27 Aug 2020 00:45:54
	System	27 Aug 2020 00:45:54

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 3'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:28', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527'	System	28 Aug 2020 02:10:07
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527' User entered 'None (0)'	System	28 Aug 2020 02:10:07
	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:38', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527' User entered 'None (0)'	System	28 Aug 2020 02:10:07
	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527' User entered 'None (0)'	System	28 Aug 2020 02:10:07
	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527' User entered 'None (0)'	System	28 Aug 2020 02:10:07
	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527'	System	28 Aug 2020 02:10:07
User entered 'None (0)'	System	28 Aug 2020 02:10:07



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:09:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527'	System	28 Aug 2020 02:10:07
User entered 'No (N)'	System	28 Aug 2020 02:10:07

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-27T22:10:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '0e294a01-7c5c-4adf-a7b7-212ebd98b527'	System	28 Aug 2020 02:10:07
User entered '27 Aug 2020 22:10'	System	28 Aug 2020 02:10:07

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 4'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'None (0)'	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:50', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'None (0)'	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:52', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'None (0)'	System	29 Aug 2020 11:59:12



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294' User entered 'None (0)'	System	29 Aug 2020 11:59:12
	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:57', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'None (0)'	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:58:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'None (0)'	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:59:03', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered 'No (N)'	System	29 Aug 2020 11:59:12

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T07:59:09', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5803a783-8a25-469b-9601-3d1cd7422294'	System	29 Aug 2020 11:59:12
User entered '29 Aug 2020 07:59'	System	29 Aug 2020 11:59:12

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 5'	System	25 Aug 2020 18:18:38



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:50', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:41:57', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:42:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'None (0)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:42:04', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered 'No (N)'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-29T22:42:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a2764aa2-620a-4049-8fc1-0f938c781491' User entered '29 Aug 2020 22:42'	System	30 Aug 2020 02:42:17
	System	30 Aug 2020 02:42:17



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 6'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:40', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:44:56', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'None (0)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:45:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered 'No (N)'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-30T21:45:07', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '617853eb-1287-451e-84bf-34d8ac57ccb5' User entered '30 Aug 2020 21:45'	System	31 Aug 2020 01:45:10
	System	31 Aug 2020 01:45:10

**US3802034**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 7'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:31', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55



US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:38', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'None (0)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:46', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered 'No (N)'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-08-31T20:57:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '40229f74-f44c-4f70-a50e-9502f124520c' User entered '31 Aug 2020 20:57'	System	01 Sep 2020 00:57:55
	System	01 Sep 2020 00:57:55

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 18:18:38

US3802034

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 18:18:38



US3802034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Emily Dougherty (b) (4)	01 Sep 2020 21:03:50

US3802034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '01 Sep 2020'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:03:50

US3802034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'Contact Made (CONTACT MADE)'	Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:03:50

US3802034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:03:50

US3802034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:03:59

**US3802034**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	01 Sep 2020 21:03:59

**US3802034**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Kumaravel Rajakumar (b) (4)	08 Sep 2020 20:36:58

US3802034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '8 Sep 2020'	(b) (4) Kumaravel Rajakumar (b) (4)	08 Sep 2020 20:36:58



**US3802034**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kumaravel Rajakumar (b) (4)	08 Sep 2020 20:36:58

US3802034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Kumaravel Rajakumar (b) (4)	08 Sep 2020 20:36:58

US3802034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Kumaravel Rajakumar (b) (4)	08 Sep 2020 20:37:07

**US3802034**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	08 Sep 2020 20:37:07

**US3802034**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	18 Sep 2020 18:29:08

US3802034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '18 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:29:08

US3802034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:29:08

US3802034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:29:08



US3802034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	18 Sep 2020 18:29:15

**US3802034**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '1'	System	18 Sep 2020 18:29:15

US3802034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	21 Sep 2020 14:04:01

US3802034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:01

US3802034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:01

**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'VISIT2'	System	21 Sep 2020 14:04:01

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59



US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '09:05'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '21 Sep 2020 09:05'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 07:51:18
Query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' answered with 'NCS' (Site from DM).	Melissa Andrasko (b) (4)	06 Oct 2020 13:59:52
User opened query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:24:32
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:24:22
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct infrared' (Site from System).	Emily Carney (b) (4)	21 Sep 2020 14:17:06
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 14:16:59
User entered '96.4' F	Emily Carney (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '61'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'bpm'	System	21 Sep 2020 14:16:59



US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '18'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'breaths/min'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '144'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '90'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59



US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '10:06'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '21 Sep 2020 10:06'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 08:33:57
Query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' answered with 'NCS' (Site from DM).	Melissa Andrasko (b) (4)	06 Oct 2020 14:00:24
User opened query 'Per CDM: Re-query: Response noted. Please confirm if result recorded is clinically significant or not. If yes, record an AE.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:24:46
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 07:24:42
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct infrared' (Site from System).	Emily Carney (b) (4)	21 Sep 2020 14:17:17
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 14:16:59
User entered '96.4' F	Emily Carney (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '65'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'bpm'	System	21 Sep 2020 14:16:59



US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '18'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'breaths/min'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '131'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '84'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	21 Sep 2020 14:16:59

US3802034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:24

US3802034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:24



US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '09:35'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '21 Sep 2020 09:35'	System	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:39



US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'ONCE'	System	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:04:39

US3802034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	21 Sep 2020 14:04:55

US3802034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:55

US3802034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '09:05'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:04:55

US3802034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '21 Sep 2020 09:05'	System	21 Sep 2020 14:04:55

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '21 Sep 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09



US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '09:19'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '21 Sep 2020 09:19'	System	21 Sep 2020 14:05:09

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

US3802034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:09

**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered empty.	System	21 Sep 2020 14:05:09

US3802034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	21 Sep 2020 14:05:21



**US3802034**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '1'	System	21 Sep 2020 14:05:21

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:10:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c47adde9-b9ae-4c70-8266-d507fcd5e32d' User entered 'Yes (Y)'	System	21 Sep 2020 14:11:18
	System	21 Sep 2020 14:11:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c47adde9-b9ae-4c70-8266-d507fcd5e32d' User entered '96.4'	System	21 Sep 2020 14:11:18
	System	21 Sep 2020 14:11:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c47adde9-b9ae-4c70-8266-d507fcd5e32d' User entered 'No (N)'	System	21 Sep 2020 14:11:18
	System	21 Sep 2020 14:11:18

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:16', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c47adde9-b9ae-4c70-8266-d507fcd5e32d' User entered '21 Sep 2020 10:11'	System	21 Sep 2020 14:11:18
	System	21 Sep 2020 14:11:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 09:55'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 12:25'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:15', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eb1ff85e-0414-48b8-b6e4-b870012d086f' User entered 'Yes (Y)'	System	22 Sep 2020 01:47:36
	System	22 Sep 2020 01:47:36

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:22', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eb1ff85e-0414-48b8-b6e4-b870012d086f' User entered '96.7'	System	22 Sep 2020 01:47:36
	System	22 Sep 2020 01:47:36

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:27', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eb1ff85e-0414-48b8-b6e4-b870012d086f' User entered 'No (N)'	System	22 Sep 2020 01:47:36
	System	22 Sep 2020 01:47:36

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:32', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'eb1ff85e-0414-48b8-b6e4-b870012d086f' User entered '21 Sep 2020 21:47'	System	22 Sep 2020 01:47:36
	System	22 Sep 2020 01:47:36

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 13:20'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 2'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5' User entered 'Yes (Y)'	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5' User entered '96.4'	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:40', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5'	System	23 Sep 2020 01:18:01
User entered 'Yes (Y)'	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant was contacted' (Site from System).	(b) (4)	29 Sep 2020 08:38:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lalicia Roman (b) (4)	28 Sep 2020 15:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5'	(b) (4)	
User entered '1'	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5' User entered '0'	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:17:56', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '58575f2b-c3d0-4429-8617-c6e199ba34b5' User entered '22 Sep 2020 21:17'	System	23 Sep 2020 01:18:01
	System	23 Sep 2020 01:18:01

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 3'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:25:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8f6e5ad9-ee0b-42d3-a89a-2176e09046c1' User entered 'Yes (Y)'	System	24 Sep 2020 01:26:07
	System	24 Sep 2020 01:26:07

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:25:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8f6e5ad9-ee0b-42d3-a89a-2176e09046c1' User entered '97.0'	System	24 Sep 2020 01:26:07
	System	24 Sep 2020 01:26:07

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:25:55', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8f6e5ad9-ee0b-42d3-a89a-2176e09046c1' User entered 'No (N)'	System	24 Sep 2020 01:26:07
	System	24 Sep 2020 01:26:07

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8f6e5ad9-ee0b-42d3-a89a-2176e09046c1' User entered '23 Sep 2020 21:26'	System	24 Sep 2020 01:26:07
	System	24 Sep 2020 01:26:07

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 4'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:55:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd471d174-9b7f-4669-947c-ddfff2f699ed'	System	25 Sep 2020 01:56:18
User entered 'Yes (Y)'	System	25 Sep 2020 01:56:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd471d174-9b7f-4669-947c-ddfff2f699ed' User entered '97.1'	System	25 Sep 2020 01:56:18
	System	25 Sep 2020 01:56:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:09', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd471d174-9b7f-4669-947c-ddfff2f699ed'	System	25 Sep 2020 01:56:18
User entered 'No (N)'	System	25 Sep 2020 01:56:18

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd471d174-9b7f-4669-947c-ddfff2f699ed'	System	25 Sep 2020 01:56:18
User entered '24 Sep 2020 21:56'	System	25 Sep 2020 01:56:18

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 5'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:43:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '696ea1f8-e87a-44a9-9c80-4f0d2afdf1c6'	System	26 Sep 2020 00:44:14
User entered 'Yes (Y)'	System	26 Sep 2020 00:44:14



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '696ea1f8-e87a-44a9-9c80-4f0d2afdf1c6'	System	26 Sep 2020 00:44:14
User entered '97.6'	System	26 Sep 2020 00:44:14

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '696ea1f8-e87a-44a9-9c80-4f0d2afdf1c6'	System	26 Sep 2020 00:44:14
User entered 'No (N)'	System	26 Sep 2020 00:44:14

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '696ea1f8-e87a-44a9-9c80-4f0d2afdf1c6'	System	26 Sep 2020 00:44:14
User entered '25 Sep 2020 20:44'	System	26 Sep 2020 00:44:14

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 6'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:31:45', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ce70fd43-6e98-46c5-bbf4-f35763ebe48b' User entered 'Yes (Y)'	System	27 Sep 2020 00:32:06
	System	27 Sep 2020 00:32:06

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:31:56', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ce70fd43-6e98-46c5-bbf4-f35763ebe48b' User entered '97.2'	System	27 Sep 2020 00:32:06
	System	27 Sep 2020 00:32:06



US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:31:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ce70fd43-6e98-46c5-bbf4-f35763ebe48b'	System	27 Sep 2020 00:32:06
User entered 'No (N)'	System	27 Sep 2020 00:32:06

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:03', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ce70fd43-6e98-46c5-bbf4-f35763ebe48b' User entered '26 Sep 2020 20:32'	System	27 Sep 2020 00:32:06
	System	27 Sep 2020 00:32:06

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 7'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:50:52', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f9cc1a80-8984-4b42-a7cd-83fd82ad365f' User entered 'Yes (Y)'	System	28 Sep 2020 01:51:15
	System	28 Sep 2020 01:51:15

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:50:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f9cc1a80-8984-4b42-a7cd-83fd82ad365f' User entered '98.2'	System	28 Sep 2020 01:51:15
	System	28 Sep 2020 01:51:15

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f9cc1a80-8984-4b42-a7cd-83fd82ad365f' User entered 'No (N)'	System	28 Sep 2020 01:51:15
	System	28 Sep 2020 01:51:15



**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:13', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f9cc1a80-8984-4b42-a7cd-83fd82ad365f' User entered '27 Sep 2020 21:51'	System	28 Sep 2020 01:51:15
	System	28 Sep 2020 01:51:15

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '20d94b25-54e9-49d5-a014-5dbaa865c7c8'	System	21 Sep 2020 14:12:02
User entered 'None (1)'	System	21 Sep 2020 14:12:02

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:45', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '20d94b25-54e9-49d5-a014-5dbaa865c7c8' User entered 'No (N)'	System	21 Sep 2020 14:12:02
	System	21 Sep 2020 14:12:02

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '20d94b25-54e9-49d5-a014-5dbaa865c7c8' User entered 'No (N)'	System	21 Sep 2020 14:12:02
	System	21 Sep 2020 14:12:02

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '20d94b25-54e9-49d5-a014-5dbaa865c7c8'	System	21 Sep 2020 14:12:02
User entered 'None (1)'	System	21 Sep 2020 14:12:02



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:11:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '20d94b25-54e9-49d5-a014-5dbaa865c7c8' User entered '21 Sep 2020 10:11'	System	21 Sep 2020 14:12:02
	System	21 Sep 2020 14:12:02

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 09:55'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 12:25'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:39', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fafb53f3-5a26-4c01-827a-efbbfb548059'	System	22 Sep 2020 01:47:59
User entered 'None (1)'	System	22 Sep 2020 01:47:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:42', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fafb53f3-5a26-4c01-827a-efbbfb548059'	System	22 Sep 2020 01:47:59
User entered 'No (N)'	System	22 Sep 2020 01:47:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fafb53f3-5a26-4c01-827a-efbbfb548059'	System	22 Sep 2020 01:47:59
User entered 'No (N)'	System	22 Sep 2020 01:47:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:52', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fafb53f3-5a26-4c01-827a-efbbfb548059'	System	22 Sep 2020 01:47:59
User entered 'None (1)'	System	22 Sep 2020 01:47:59



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:47:57', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fafb53f3-5a26-4c01-827a-efbbfb548059'	System	22 Sep 2020 01:47:59
User entered '21 Sep 2020 21:47'	System	22 Sep 2020 01:47:59

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 13:20'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 2'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1af40129-d3a7-4ffb-bc17-518cbe37409a'	System	23 Sep 2020 01:18:21
User entered 'None (1)'	System	23 Sep 2020 01:18:21

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:07', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1af40129-d3a7-4ffb-bc17-518cbe37409a' User entered 'No (N)'	System	23 Sep 2020 01:18:21
	System	23 Sep 2020 01:18:21

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:10', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1af40129-d3a7-4ffb-bc17-518cbe37409a' User entered 'No (N)'	System	23 Sep 2020 01:18:21
	System	23 Sep 2020 01:18:21

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1af40129-d3a7-4ffb-bc17-518cbe37409a'	System	23 Sep 2020 01:18:21
User entered 'None (1)'	System	23 Sep 2020 01:18:21



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1af40129-d3a7-4ffb-bc17-518cbe37409a' User entered '22 Sep 2020 21:18'	System	23 Sep 2020 01:18:21
	System	23 Sep 2020 01:18:21

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 3'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c495e103-a6cc-4b6d-9d8c-4044e71a1b22'	System	24 Sep 2020 01:26:33
User entered 'None (1)'	System	24 Sep 2020 01:26:33

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:11', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c495e103-a6cc-4b6d-9d8c-4044e71a1b22'	System	24 Sep 2020 01:26:33
User entered 'No (N)'	System	24 Sep 2020 01:26:33

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c495e103-a6cc-4b6d-9d8c-4044e71a1b22'	System	24 Sep 2020 01:26:33
User entered 'No (N)'	System	24 Sep 2020 01:26:33

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c495e103-a6cc-4b6d-9d8c-4044e71a1b22'	System	24 Sep 2020 01:26:33
User entered 'None (1)'	System	24 Sep 2020 01:26:33



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:26', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c495e103-a6cc-4b6d-9d8c-4044e71a1b22'	System	24 Sep 2020 01:26:33
User entered '23 Sep 2020 21:26'	System	24 Sep 2020 01:26:33

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 4'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '078a3b5d-dc2c-4ac2-932c-d8dd5f516897'	System	25 Sep 2020 01:56:42
User entered 'None (1)'	System	25 Sep 2020 01:56:42

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:23', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '078a3b5d-dc2c-4ac2-932c-d8dd5f516897'	System	25 Sep 2020 01:56:42
User entered 'No (N)'	System	25 Sep 2020 01:56:42

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:27', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '078a3b5d-dc2c-4ac2-932c-d8dd5f516897' User entered 'No (N)'	System	25 Sep 2020 01:56:42
	System	25 Sep 2020 01:56:42

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '078a3b5d-dc2c-4ac2-932c-d8dd5f516897'	System	25 Sep 2020 01:56:42
User entered 'None (1)'	System	25 Sep 2020 01:56:42



**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:39', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '078a3b5d-dc2c-4ac2-932c-d8dd5f516897'	System	25 Sep 2020 01:56:42
User entered '24 Sep 2020 21:56'	System	25 Sep 2020 01:56:42

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 5'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e8a3294-88c0-48bf-a8c6-0d8a67f655f1'	System	26 Sep 2020 00:44:44
User entered 'None (1)'	System	26 Sep 2020 00:44:44

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:23', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e8a3294-88c0-48bf-a8c6-0d8a67f655f1' User entered 'No (N)'	System	26 Sep 2020 00:44:44
	System	26 Sep 2020 00:44:44

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:26', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e8a3294-88c0-48bf-a8c6-0d8a67f655f1' User entered 'No (N)'	System	26 Sep 2020 00:44:44
	System	26 Sep 2020 00:44:44

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e8a3294-88c0-48bf-a8c6-0d8a67f655f1'	System	26 Sep 2020 00:44:44
User entered 'None (1)'	System	26 Sep 2020 00:44:44



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e8a3294-88c0-48bf-a8c6-0d8a67f655f1'	System	26 Sep 2020 00:44:44
User entered '25 Sep 2020 20:44'	System	26 Sep 2020 00:44:44

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 6'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f746b991-c57d-420a-966a-dca66697927f' User entered 'None (1)'	System	27 Sep 2020 00:32:30
	System	27 Sep 2020 00:32:30

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:15', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f746b991-c57d-420a-966a-dca66697927f' User entered 'No (N)'	System	27 Sep 2020 00:32:30
	System	27 Sep 2020 00:32:30

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:18', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f746b991-c57d-420a-966a-dca66697927f' User entered 'No (N)'	System	27 Sep 2020 00:32:30
	System	27 Sep 2020 00:32:30

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:21', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f746b991-c57d-420a-966a-dca66697927f' User entered 'None (1)'	System	27 Sep 2020 00:32:30
	System	27 Sep 2020 00:32:30



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:26', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f746b991-c57d-420a-966a-dca66697927f' User entered '26 Sep 2020 20:32'	System	27 Sep 2020 00:32:30
	System	27 Sep 2020 00:32:30

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 7'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:18', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '94a4b298-aa22-443a-8013-09166149e231'	System	28 Sep 2020 01:51:37
User entered 'None (1)'	System	28 Sep 2020 01:51:37

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:21', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '94a4b298-aa22-443a-8013-09166149e231' User entered 'No (N)'	System	28 Sep 2020 01:51:37
	System	28 Sep 2020 01:51:37

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '94a4b298-aa22-443a-8013-09166149e231' User entered 'No (N)'	System	28 Sep 2020 01:51:37
	System	28 Sep 2020 01:51:37

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:28', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '94a4b298-aa22-443a-8013-09166149e231'	System	28 Sep 2020 01:51:37
User entered 'None (1)'	System	28 Sep 2020 01:51:37



US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '94a4b298-aa22-443a-8013-09166149e231' User entered '27 Sep 2020 21:51'	System	28 Sep 2020 01:51:37
	System	28 Sep 2020 01:51:37

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:03', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8' User entered 'None (0)'	System	21 Sep 2020 14:12:32
	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8' User entered 'None (0)'	System	21 Sep 2020 14:12:32
	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:09', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8'	System	21 Sep 2020 14:12:32
User entered 'None (0)'	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:12', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8' User entered 'None (0)'	System	21 Sep 2020 14:12:32
	System	21 Sep 2020 14:12:32



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8' User entered 'None (0)'	System	21 Sep 2020 14:12:32
	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:17', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8' User entered 'None (0)'	System	21 Sep 2020 14:12:32
	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:20', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8'	System	21 Sep 2020 14:12:32
User entered 'No (N)'	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T10:12:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7e62a2cc-bc56-43bb-a01f-2694e7fa79f8'	System	21 Sep 2020 14:12:32
User entered '21 Sep 2020 10:12'	System	21 Sep 2020 14:12:32

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 09:55'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 12:25'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02'	System	22 Sep 2020 01:48:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 01:48:52



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:16', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02' User entered 'None (0)'	System	22 Sep 2020 01:48:52
	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02'	System	22 Sep 2020 01:48:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02' User entered 'None (0)'	System	22 Sep 2020 01:48:52
	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:37', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02' User entered 'None (0)'	System	22 Sep 2020 01:48:52
	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:40', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02' User entered 'None (0)'	System	22 Sep 2020 01:48:52
	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02'	System	22 Sep 2020 01:48:52
User entered 'No (N)'	System	22 Sep 2020 01:48:52

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-21T21:48:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3b572143-ff29-4351-afa8-2b6a77963c02'	System	22 Sep 2020 01:48:52
User entered '21 Sep 2020 21:48'	System	22 Sep 2020 01:48:52

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '21 Sep 2020 13:20'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 2'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:28', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578'	System	23 Sep 2020 01:19:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:45', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578'	System	23 Sep 2020 01:19:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:18:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578' User entered 'None (0)'	System	23 Sep 2020 01:19:37
	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:19:06', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578'	System	23 Sep 2020 01:19:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:19:09', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578' User entered 'None (0)'	System	23 Sep 2020 01:19:37
	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:19:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578'	System	23 Sep 2020 01:19:37
User entered 'No interference with activity (1)'	System	23 Sep 2020 01:19:37



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:19:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578' User entered 'No (N)'	System	23 Sep 2020 01:19:37
	System	23 Sep 2020 01:19:37

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-22T21:19:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '15e147ba-b2f6-41f0-9fd8-4bee88b81578' User entered '22 Sep 2020 21:19'	System	23 Sep 2020 01:19:37
	System	23 Sep 2020 01:19:37

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 3'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:36', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:39', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'None (0)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered 'No (N)'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-23T21:26:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8e3a5553-e895-48e1-9057-5a3d42c803a9' User entered '23 Sep 2020 21:26'	System	24 Sep 2020 01:26:55
	System	24 Sep 2020 01:26:55

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 4'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:51', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:55', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:56:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:57:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'None (0)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:57:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered 'No (N)'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-24T21:57:18', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f5fdeba0-77e1-4e17-8154-336bcae47a83' User entered '24 Sep 2020 21:57'	System	25 Sep 2020 01:57:22
	System	25 Sep 2020 01:57:22



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 5'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:50', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:56', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:44:59', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:45:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'None (0)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:45:05', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered 'No (N)'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-25T20:45:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ad24dea9-c3db-4a21-8376-8ba6be08e76a' User entered '25 Sep 2020 20:45'	System	26 Sep 2020 00:45:21
	System	26 Sep 2020 00:45:21

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 6'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:31', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068'	System	27 Sep 2020 00:33:16
User entered 'None (0)'	System	27 Sep 2020 00:33:16

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068'	System	27 Sep 2020 00:33:16
User entered 'None (0)'	System	27 Sep 2020 00:33:16



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:36', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068' User entered 'None (0)'	System	27 Sep 2020 00:33:16
	System	27 Sep 2020 00:33:16

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:39', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068' User entered 'None (0)'	System	27 Sep 2020 00:33:16
	System	27 Sep 2020 00:33:16

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068' User entered 'None (0)'	System	27 Sep 2020 00:33:16
	System	27 Sep 2020 00:33:16

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 17:46:30**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068' User entered 'None (0)'	System	27 Sep 2020 00:33:16
	System	27 Sep 2020 00:33:16

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:32:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068'	System	27 Sep 2020 00:33:16
User entered 'No (N)'	System	27 Sep 2020 00:33:16

**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-26T20:33:15', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cee92dd-f389-4b1f-9cf1-060c4d0cb068' User entered '26 Sep 2020 20:33'	System	27 Sep 2020 00:33:16
	System	27 Sep 2020 00:33:16

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:04:39



US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	21 Sep 2020 14:04:39
User entered 'Day 7'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:38', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289'	System	28 Sep 2020 01:52:04
User entered 'None (0)'	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289'	System	28 Sep 2020 01:52:04
User entered 'None (0)'	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289' User entered 'None (0)'	System	28 Sep 2020 01:52:04
	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:47', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289' User entered 'None (0)'	System	28 Sep 2020 01:52:04
	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:49', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289' User entered 'None (0)'	System	28 Sep 2020 01:52:04
	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:52', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289'	System	28 Sep 2020 01:52:04
User entered 'None (0)'	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:51:55', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289'	System	28 Sep 2020 01:52:04
User entered 'No (N)'	System	28 Sep 2020 01:52:04



**US3802034**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 17:46:30**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-09-27T21:52:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '3905dc8b-013d-4345-aeaf-6db93538f289' User entered '27 Sep 2020 21:52'	System	28 Sep 2020 01:52:04
	System	28 Sep 2020 01:52:04

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:04:39

US3802034

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 17:46:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:04:39

**US3802034**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	28 Sep 2020 15:38:34

US3802034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '28 Sep 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	28 Sep 2020 15:38:34

US3802034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	28 Sep 2020 15:38:34

US3802034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	28 Sep 2020 15:38:34

US3802034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	28 Sep 2020 15:38:38



**US3802034**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	28 Sep 2020 15:38:38

US3802034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	05 Oct 2020 19:09:22

US3802034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	05 Oct 2020 19:09:22

US3802034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Contact Made (CONTACT MADE)'	Dominic Kramer (b) (4) (b) (4)	05 Oct 2020 19:09:22

US3802034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Dominic Kramer (b) (4)	05 Oct 2020 19:09:22

US3802034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	05 Oct 2020 19:09:27

**US3802034**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	05 Oct 2020 19:09:27

US3802034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	12 Oct 2020 18:15:02



US3802034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '12 Oct 2020'	(b) (4) Dominic Kramer (b) (4)	12 Oct 2020 18:15:02

**US3802034**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dominic Kramer (b) (4)	12 Oct 2020 18:15:02

US3802034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Dominic Kramer (b) (4)	12 Oct 2020 18:15:02

US3802034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	12 Oct 2020 18:14:52

**US3802034**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	12 Oct 2020 18:14:52

US3802034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	19 Oct 2020 17:24:46

US3802034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '19 Oct 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:24:46

US3802034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:24:46



**US3802034**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'VISIT3'	System	19 Oct 2020 17:24:46

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '19 Oct 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '12:59'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

**US3802034**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '19 Oct 2020 12:59'	System	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '97.5' F	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28



**US3802034**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '60'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'bpm'	System	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '16'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'breaths/min'	System	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '118'	(b) (4) Emily Carney (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '73'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:28

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'mmHg'	System	19 Oct 2020 17:25:28



US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54

US3802034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54

US3802034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:37

US3802034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:37

US3802034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	19 Oct 2020 17:25:51

US3802034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '19 Oct 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:51

US3802034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '13:06'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:51

US3802034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered '19 Oct 2020 13:06'	System	19 Oct 2020 17:25:51



US3802034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Oct 2020 17:25:55

**US3802034**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	19 Oct 2020 17:25:55

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 64'	System	25 Aug 2020 18:18:38

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-10-25T06:06:54', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e820228b-0ecd-49a2-a5af-79767a00a1f2'	System	25 Oct 2020 10:07:09
User entered 'No (N)'	System	25 Oct 2020 10:07:09

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

Have you been exposed to someone with 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)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-10-25T06:07:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e820228b-0ecd-49a2-a5af-79767a00a1f2'	System	25 Oct 2020 10:07:09
User entered 'No (N)'	System	25 Oct 2020 10:07:09

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-10-25T06:07:08', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'e820228b-0ecd-49a2-a5af-79767a00a1f2' User entered '25 Oct 2020 06:07:08'	System	25 Oct 2020 10:07:09
	System	25 Oct 2020 10:07:09

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 18:18:38

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:10:26
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 18:18:38



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 71'	System	25 Aug 2020 18:18:38

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

Have you been exposed to someone with 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 18:18:38

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 18:18:38

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered 'Day 78'	System	25 Aug 2020 18:18:38

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

Have you been exposed to someone with 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28



US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

US3802034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

[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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Please 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)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 18:18:38

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:30:28
Data entry locked.	System	25 Aug 2020 18:18:38
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 18:18:38



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-22T19:41:35', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7da0d58b-194a-43a4-b6bf-66b923da9440'	System	23 Nov 2020 00:41:57
User entered 'No (N)'	System	23 Nov 2020 00:41:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-22T19:41:43', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7da0d58b-194a-43a4-b6bf-66b923da9440'	System	23 Nov 2020 00:41:57
User entered 'No (N)'	System	23 Nov 2020 00:41:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-22T19:41:55', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7da0d58b-194a-43a4-b6bf-66b923da9440' User entered '22 Nov 2020 19:41:55'	System	23 Nov 2020 00:41:57
	System	23 Nov 2020 00:41:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-28T12:24:18', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd599ab20-bb00-482b-8105-fa8f7f789594'	System	28 Nov 2020 17:24:32
User entered 'No (N)'	System	28 Nov 2020 17:24:32



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-28T12:24:25', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd599ab20-bb00-482b-8105-fa8f7f789594'	System	28 Nov 2020 17:24:32
User entered 'No (N)'	System	28 Nov 2020 17:24:32

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-11-28T12:24:30', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'd599ab20-bb00-482b-8105-fa8f7f789594'	System	28 Nov 2020 17:24:32
User entered '28 Nov 2020 12:24:30'	System	28 Nov 2020 17:24:32

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-06T17:59:33', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8c622f65-2e1b-42b0-b7a1-61976c688035'	System	06 Dec 2020 22:59:46
User entered 'No (N)'	System	06 Dec 2020 22:59:46

US3802034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 17:46:30

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-06T17:59:38', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8c622f65-2e1b-42b0-b7a1-61976c688035'	System	06 Dec 2020 22:59:46
User entered 'No (N)'	System	06 Dec 2020 22:59:46

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-06T17:59:44', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '8c622f65-2e1b-42b0-b7a1-61976c688035' User entered '06 Dec 2020 17:59:44'	System	06 Dec 2020 22:59:46
	System	06 Dec 2020 22:59:46



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-10T06:59:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '46de4b60-8185-43a5-aff5-a77c35a076b9' User entered 'No (N)'	System	10 Dec 2020 11:59:33
	System	10 Dec 2020 11:59:33

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-10T06:59:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '46de4b60-8185-43a5-aff5-a77c35a076b9' User entered 'No (N)'	System	10 Dec 2020 11:59:33
	System	10 Dec 2020 11:59:33

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-10T06:59:31', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '46de4b60-8185-43a5-aff5-a77c35a076b9' User entered '10 Dec 2020 06:59:31'	System	10 Dec 2020 11:59:33
	System	10 Dec 2020 11:59:33

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-18T06:18:53', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1d4a1a48-82c3-43a3-9206-aeb5a003f1ff' User entered 'No (N)'	System	18 Dec 2020 11:19:07
	System	18 Dec 2020 11:19:07

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-18T06:18:58', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1d4a1a48-82c3-43a3-9206-aeb5a003f1ff' User entered 'No (N)'	System	18 Dec 2020 11:19:07
	System	18 Dec 2020 11:19:07

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-18T06:19:02', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1d4a1a48-82c3-43a3-9206-aeb5a003f1ff' User entered '18 Dec 2020 06:19:02'	System	18 Dec 2020 11:19:07
	System	18 Dec 2020 11:19:07

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-27T18:31:17', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7c102257-7479-410d-9e7c-10d5c8fc4469' User entered 'No (N)'	System	27 Dec 2020 23:31:32
	System	27 Dec 2020 23:31:32



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-27T18:31:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7c102257-7479-410d-9e7c-10d5c8fc4469' User entered 'No (N)'	System	27 Dec 2020 23:31:32
	System	27 Dec 2020 23:31:32

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-27T18:31:29', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '7c102257-7479-410d-9e7c-10d5c8fc4469' User entered '27 Dec 2020 18:31:29'	System	27 Dec 2020 23:31:32
	System	27 Dec 2020 23:31:32

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-31T10:54:10', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1c035dd8-146b-4dc2-a74b-9ffc2054d3e3' User entered 'No (N)'	System	31 Dec 2020 15:54:23
	System	31 Dec 2020 15:54:23

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-31T10:54:16', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1c035dd8-146b-4dc2-a74b-9ffc2054d3e3'	System	31 Dec 2020 15:54:23
User entered 'No (N)'	System	31 Dec 2020 15:54:23

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2020-12-31T10:54:20', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '1c035dd8-146b-4dc2-a74b-9ffc2054d3e3' User entered '31 Dec 2020 10:54:20'	System	31 Dec 2020 15:54:23
	System	31 Dec 2020 15:54:23



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-17T17:59:19', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f3c94981-fd34-412d-bd67-f2d9a3d040fd' User entered 'No (N)'	System	17 Jan 2021 22:59:35
	System	17 Jan 2021 22:59:35

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-17T17:59:26', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f3c94981-fd34-412d-bd67-f2d9a3d040fd'	System	17 Jan 2021 22:59:35
User entered 'No (N)'	System	17 Jan 2021 22:59:35



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-17T17:59:32', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f3c94981-fd34-412d-bd67-f2d9a3d040fd' User entered '17 Jan 2021 17:59:32'	System	17 Jan 2021 22:59:35
	System	17 Jan 2021 22:59:35

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-25T03:52:24', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '82b3af71-9261-4ec0-83c5-bee972c46b15'	System	25 Jan 2021 08:52:37
User entered 'No (N)'	System	25 Jan 2021 08:52:37

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-25T03:52:31', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '82b3af71-9261-4ec0-83c5-bee972c46b15'	System	25 Jan 2021 08:52:37
User entered 'No (N)'	System	25 Jan 2021 08:52:37

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-25T03:52:35', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '82b3af71-9261-4ec0-83c5-bee972c46b15' User entered '25 Jan 2021 03:52:35'	System	25 Jan 2021 08:52:37
	System	25 Jan 2021 08:52:37

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-28T16:44:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '4c846ce6-28d4-4524-ad45-13cfa79cc427'	System	28 Jan 2021 21:44:57
User entered 'No (N)'	System	28 Jan 2021 21:44:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-28T16:44:37', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '4c846ce6-28d4-4524-ad45-13cfa79cc427'	System	28 Jan 2021 21:44:57
User entered 'Yes (Y)'	System	28 Jan 2021 21:44:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-28T16:44:41', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '4c846ce6-28d4-4524-ad45-13cfa79cc427'	System	28 Jan 2021 21:44:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 21:44:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-01-28T16:44:48', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '4c846ce6-28d4-4524-ad45-13cfa79cc427' User entered '28 Jan 2021 16:44:48'	System	28 Jan 2021 21:44:57
	System	28 Jan 2021 21:44:57

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-06T13:24:01', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '52201d1c-eb0d-4299-ab95-cf775883190c' User entered 'No (N)'	System	06 Feb 2021 18:24:46
	System	06 Feb 2021 18:24:46

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-06T13:24:07', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '52201d1c-eb0d-4299-ab95-cf775883190c' User entered 'No (N)'	System	06 Feb 2021 18:24:46
	System	06 Feb 2021 18:24:46

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-06T13:24:14', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '52201d1c-eb0d-4299-ab95-cf775883190c' User entered '06 Feb 2021 13:24:14'	System	06 Feb 2021 18:24:46
	System	06 Feb 2021 18:24:46

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-18T10:01:23', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f096a280-7d6b-4f9c-adb7-473bd7dd89d1' User entered 'No (N)'	System	18 Feb 2021 15:01:41
	System	18 Feb 2021 15:01:41

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-18T10:01:29', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f096a280-7d6b-4f9c-adb7-473bd7dd89d1' User entered 'No (N)'	System	18 Feb 2021 15:01:41
	System	18 Feb 2021 15:01:41

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-18T10:01:34', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f096a280-7d6b-4f9c-adb7-473bd7dd89d1'	System	18 Feb 2021 15:01:41
User entered '18 Feb 2021 10:01:34'	System	18 Feb 2021 15:01:41

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-27T12:00:28-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ae290ed3-324b-4144-a24d-09777e884633'	System	27 Feb 2021 17:03:31
User entered 'No (N)'	System	27 Feb 2021 17:03:31

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-27T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ae290ed3-324b-4144-a24d-09777e884633'	System	27 Feb 2021 17:03:31
User entered 'No (N)'	System	27 Feb 2021 17:03:31

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-02-27T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'ae290ed3-324b-4144-a24d-09777e884633'	System	27 Feb 2021 17:03:31
User entered '27 Feb 2021 17:00:38'	System	27 Feb 2021 17:03:31

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-08T15:37:28-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2b66ce3d-efc9-4b41-91ab-8c4614f0c2c2'	System	08 Mar 2021 20:37:43
User entered 'No (N)'	System	08 Mar 2021 20:37:43

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-08T15:37:32-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2b66ce3d-efc9-4b41-91ab-8c4614f0c2c2'	System	08 Mar 2021 20:37:43
User entered 'No (N)'	System	08 Mar 2021 20:37:43



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-08T15:37:38-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '2b66ce3d-efc9-4b41-91ab-8c4614f0c2c2'	System	08 Mar 2021 20:37:43
User entered '08 Mar 2021 15:37:38'	System	08 Mar 2021 20:37:43

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-18T06:43:30-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a75d96c0-137a-451b-9a81-d5f4f369ddc7'	System	29 Mar 2021 10:05:18
User entered 'No (N)'	System	29 Mar 2021 10:05:18



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-18T06:43:38-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a75d96c0-137a-451b-9a81-d5f4f369ddc7'	System	29 Mar 2021 10:05:18
User entered 'No (N)'	System	29 Mar 2021 10:05:18

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-18T06:43:42-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a75d96c0-137a-451b-9a81-d5f4f369ddc7'	System	29 Mar 2021 10:05:18
User entered '18 Mar 2021 06:43:42'	System	29 Mar 2021 10:05:18

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-29T06:05:28-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cf079db-72f2-4191-a1cb-3add64d0c888'	System	29 Mar 2021 10:05:54
User entered 'No (N)'	System	29 Mar 2021 10:05:54

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-29T06:05:36-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cf079db-72f2-4191-a1cb-3add64d0c888'	System	29 Mar 2021 10:05:54
User entered 'No (N)'	System	29 Mar 2021 10:05:54

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-29T06:05:49-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '5cf079db-72f2-4191-a1cb-3add64d0c888' User entered '29 Mar 2021 06:05:49'	System	29 Mar 2021 10:05:54
	System	29 Mar 2021 10:05:54



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-04T06:35:44-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f330e546-1336-4a20-a3e5-c6b6576a82f6'	System	10 Apr 2021 01:01:49
User entered 'No (N)'	System	10 Apr 2021 01:01:49

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-04T06:35:52-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f330e546-1336-4a20-a3e5-c6b6576a82f6' User entered 'No (N)'	System	10 Apr 2021 01:01:49

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-04T06:35:57-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'f330e546-1336-4a20-a3e5-c6b6576a82f6' User entered '04 Apr 2021 06:35:57'	System	10 Apr 2021 01:01:49
	System	10 Apr 2021 01:01:49

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:30:28

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-09T21:00:27-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c642bd63-6dfb-4b42-a563-e9579c02ed4c' User entered 'No (N)'	System	10 Apr 2021 01:04:14
	System	10 Apr 2021 01:04:14

**US3802034**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-09T21:00:29-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c642bd63-6dfb-4b42-a563-e9579c02ed4c' User entered 'No (N)'	System	10 Apr 2021 01:04:14

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-09T21:00:40-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'c642bd63-6dfb-4b42-a563-e9579c02ed4c' User entered '09 Apr 2021 21:00:40'	System	10 Apr 2021 01:04:14
	System	10 Apr 2021 01:04:14

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-15T07:28:35-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '00d265b4-86e4-4112-9903-6e5327d21f01'	System	22 Apr 2021 10:10:25
User entered 'No (N)'	System	22 Apr 2021 10:10:25



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-15T07:28:40-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '00d265b4-86e4-4112-9903-6e5327d21f01'	System	22 Apr 2021 10:10:25
User entered 'No (N)'	System	22 Apr 2021 10:10:25

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-15T07:28:43-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '00d265b4-86e4-4112-9903-6e5327d21f01'	System	22 Apr 2021 10:10:25
User entered '15 Apr 2021 07:28:43'	System	22 Apr 2021 10:10:25

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-22T06:10:29-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a9940f6f-4b84-4833-a4bb-a531f1a38d8d'	System	01 May 2021 16:32:08
User entered 'No (N)'	System	01 May 2021 16:32:08

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-22T06:10:36-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a9940f6f-4b84-4833-a4bb-a531f1a38d8d'	System	01 May 2021 16:32:08
User entered 'No (N)'	System	01 May 2021 16:32:08

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-04-22T06:10:40-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'a9940f6f-4b84-4833-a4bb-a531f1a38d8d'	System	01 May 2021 16:32:08
User entered '22 Apr 2021 06:10:40'	System	01 May 2021 16:32:08



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-05-01T12:31:55-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '55db141d-e1ef-4a1b-b250-161a41cf156e' User entered 'No (N)'	System	01 May 2021 16:32:40
	System	01 May 2021 16:32:40

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

Have you been exposed to someone with 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 (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-05-01T12:32:00-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '55db141d-e1ef-4a1b-b250-161a41cf156e'	System	01 May 2021 16:32:40
User entered 'No (N)'	System	01 May 2021 16:32:40

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-05-01T12:32:06-04:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: '55db141d-e1ef-4a1b-b250-161a41cf156e' User entered '01 May 2021 12:32:06'	System	01 May 2021 16:32:40
	System	01 May 2021 16:32:40

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:30:28



**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:30:28

**US3802034**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 17:46:30**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:30:28
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:30:28

US3802034

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 17:46:30**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-08T15:37:48-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fe57de22-9081-4a8e-b685-ef75b1f5d8c4'	System	29 Mar 2021 10:05:18
User entered 'No (N)'	System	29 Mar 2021 10:05:18

**US3802034**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:05:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B2A467-4685-4D3C-94D0-66DD6A5D3CC5)', Time: '2021-03-08T15:37:52-05:00', User OID: 'PatientReportedOutcome (US3802034)', ODM File OID: 'fe57de22-9081-4a8e-b685-ef75b1f5d8c4'	System	29 Mar 2021 10:05:18
User entered '08 Mar 2021 15:37:52'	System	29 Mar 2021 10:05:18

US3802034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:29:16

**US3802034**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '16 Nov 2020'	(b) (4) Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:29:16

**US3802034**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4)	16 Nov 2020 19:29:16

US3802034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Emily Carney (b) (4)	16 Nov 2020 19:29:16
	(b) (4)	



US3802034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:29:23

**US3802034**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:11:54
User entered 'I'	System	16 Nov 2020 19:29:23

**US3802034**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:37:42

**US3802034**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '21 Dec 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:37:42

US3802034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:37:42

**US3802034**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:37:42

**US3802034**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:37:48

**US3802034**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'I'	System	21 Dec 2020 15:37:48



**US3802034**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	19 Jan 2021 19:58:01

US3802034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '19 Jan 2021'	(b) (4) Lisa Vavro (b) (4) (b) (4)	19 Jan 2021 19:58:01

**US3802034**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	19 Jan 2021 19:58:01

US3802034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Lisa Vavro (b) (4) (b) (4)	19 Jan 2021 19:58:01

US3802034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Lisa Vavro (b) (4) (b) (4)	19 Jan 2021 19:58:06

**US3802034**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'I'	System	19 Jan 2021 19:58:06

**US3802034**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	18 Feb 2021 14:41:54

**US3802034**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
User entered '18 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	18 Feb 2021 14:41:54



US3802034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4)	18 Feb 2021 14:41:54

US3802034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
User entered empty.	(b) (4) Emily Carney (b) (4)	18 Feb 2021 14:41:54

US3802034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	18 Feb 2021 14:42:00

**US3802034**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'I'	System	18 Feb 2021 14:42:00

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:29

US3802034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you' canceled (Site from DM).		29 Mar 2021 23:04:39
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you' (Site from DM).		29 Mar 2021 17:53:55
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '17 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:29
	(b) (4)	

US3802034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:35:29

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'VISIT4'	System	17 Mar 2021 13:35:29



US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '17 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '09:10'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered '17 Mar 2021 09:10'	System	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '97.9' F	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '66'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47



**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'bpm'	System	31 Mar 2021 12:46:47

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '18'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'breaths/min'	System	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '133'	(b) (4) Emily Carney (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'mmHg'	System	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:44:52
User entered '83'	(b) (4) Emily Carney (b) (4) (b) (4)	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'mmHg'	System	31 Mar 2021 12:46:47

US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20



US3802034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20

US3802034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:33
	(b) (4)	

US3802034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered empty.	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:33
	(b) (4)	

US3802034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:35:49

US3802034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '17 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:49
	(b) (4)	

US3802034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '09:22'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:35:49
	(b) (4)	

**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered '17 Mar 2021 09:22'	System	17 Mar 2021 13:35:49

US3802034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:35:54



**US3802034**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:01:20
User entered 'I'	System	17 Mar 2021 13:35:54

**US3802034**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	20 Apr 2021 15:11:03
	(b) (4)	
User entered 'Yes (Y)'	Emily Carney (b) (4)	19 Apr 2021 18:49:11
	(b) (4)	

**US3802034**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	20 Apr 2021 15:11:03
	(b) (4)	
User entered '19 Apr 2021'	Emily Carney (b) (4)	19 Apr 2021 18:49:11
	(b) (4)	

**US3802034**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	20 Apr 2021 15:11:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	19 Apr 2021 18:49:11

US3802034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4) (b) (4)	20 Apr 2021 15:11:03
User entered empty.	Emily Carney (b) (4) (b) (4)	19 Apr 2021 18:49:11

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	20 Apr 2021 15:11:03
	(b) (4)	
User entered 'Yes (Y)'	Emily Carney (b) (4)	19 Apr 2021 18:49:19
	(b) (4)	

**US3802034**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 18:49:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 17:46:30

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:03
DataPoint Verified.		17 Nov 2020 15:48:29
User closed query 'Per ETRTR: Please complete data entry in COVID-19 Severity Assessment Page, thanks' (Site from CRA).		15 Nov 2020 21:11:12
Query 'Per ETRTR: Please complete data entry in COVID-19 Severity Assessment Page, thanks' answered with 'completed severity assessment form' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 20:05:33
User opened query 'Per ETRTR: Please complete data entry in COVID-19 Severity Assessment Page, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:33:29
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:26:30



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 17:46:30

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:03
DataPoint Verified.		17 Nov 2020 15:48:29
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '11:02' reason for change: Data Entry Error	System	05 Nov 2020 16:26:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jennifer Nagg (b) (4)	05 Nov 2020 16:26:38
User entered '11:' (non-conformant).	(b) (4)	
	System	05 Nov 2020 16:26:30
	Jennifer Nagg (b) (4)	05 Nov 2020 16:26:30
	(b) (4)	

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Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 17:46:30

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:03
User entered '5 Nov 2020 11:02'	System	05 Nov 2020 16:26:38
User entered '5 Nov 2020 11:.' (non-conformant).	System	05 Nov 2020 16:26:30

**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 17:46:30**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:03
DataPoint Verified.		17 Nov 2020 15:48:29
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Jennifer Nagg (b) (4)	05 Nov 2020 16:26:30

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Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 17:46:30

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:03
DataPoint Verified.		17 Nov 2020 15:48:29
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:26:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Day 1 (Day 1)'	(b) (4) Jennifer Nagg (b) (4)	05 Nov 2020 16:29:19

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:50:41
User closed query 'Per ETRTR: Per guidelines, please add Symptoms reported prior to 05Nov20 Illness Visit Day 1, thanks.' (Site from CRA).		15 Nov 2020 21:11:22
Query 'Per ETRTR: Per guidelines, please add Symptoms reported prior to 05Nov20 Illness Visit Day 1, thanks.' answered with 'this was the first day or reported symptoms by subject' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:28:17
User opened query 'Per ETRTR: Per guidelines, please add Symptoms reported prior to 05Nov20 Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:32:13
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:04
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '97'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:08
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '98.5' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:16
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:21
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Moderate (Moderate)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:24
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:26
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:30
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:38
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:41
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:45
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:47
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:49
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:51:58
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:52:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:52:04
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:52:06
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:52:12
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 15:52:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:29:19

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Day 2 (Day 2)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 16:02:20

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:03:52
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '6 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:03:57
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '98'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	09 Nov 2020 16:02:20

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:04
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '97.4' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:06
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:11
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:05:00
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:57
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:55
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:53
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:51
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:49
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:47
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:44
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:23
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:41
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:38
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:36
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:33
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:04:31
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:02:20



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Day 3 (Day 3)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:06:45
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '7 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:18
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:06:52
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '98'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:16
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '97.4' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:00
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:11
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:09
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:08
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:04
DataPoint Un-verified.		17 Nov 2020 16:08:02
DataPoint Verified.		17 Nov 2020 16:07:57
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:55
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:53
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:35
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:20
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:32
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:29
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:27
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:07:23
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:03:54

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Day 4 (Day 4)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		19 Nov 2020 03:11:31
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '8 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		19 Nov 2020 03:11:35
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:56
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '98'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 12 Aug 2021 17:46:30**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:08:58
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '97.6' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:30
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:33
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:36
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:40
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:43
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:45
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:47
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:55
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Moderate (Moderate)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:09:58
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:00
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:08
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Moderate (Moderate)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:14
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:16
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:19
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:23
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		17 Nov 2020 16:10:26
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 16:06:41

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 5 (Day 5)'	(b) (4) Jennifer Nagg (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:14:25
User entered '9 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:18
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:21
User entered '97'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42



**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 12 Aug 2021 17:46:30**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:43
User entered '97.9' F	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:51
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:15:54
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:07
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:09
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:29
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:34
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:43
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:50
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:55
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:16:58
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:10
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:15
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:22
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:24
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:29
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:17:31
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	10 Nov 2020 16:12:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 6 (Day 6)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:20:34
User entered '10 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 03:11:16
User entered '0'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:20:38
User entered '99'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:26:49
User entered '100' F	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:26:58
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:00
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:06
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:08
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:15
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:25
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:28
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:36
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:40
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:27:43
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:10
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:14
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:22
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:29
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:36
DataPoint Un-verified.		17 Nov 2020 16:28:35
DataPoint Verified.		17 Nov 2020 16:28:31
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:28:26
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	11 Nov 2020 21:02:59



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 7 (Day 7)'	(b) (4) Jennifer Nagg (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:30:11
User entered '11 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:52:31
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:52:47
User entered '98'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:52:51
User entered '99.8' F	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:52:54
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:52:57
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:01
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:05
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:13
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:21
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:23
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:34
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:48
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:53:50
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:11
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:16
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:21
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:22
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:24
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:54:29
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:47:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 8 (Day 8)'	(b) (4) Jennifer Nagg (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:55:03
User entered '12 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:55:06
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:55:10
User entered '98'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	13 Nov 2020 19:51:06

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:16
User entered '98.6' F	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:21
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:24
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:31
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:37
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:56:47
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 02:13:00
User closed query 'source states "none" . please confirm. ' (Site from CRA).		18 Nov 2020 02:12:59
Query 'source states "none" . please confirm. ' answered with 'done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:16:31
User entered 'None (None)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:16:26
User opened query 'source states "none" . please confirm. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 16:57:26
DataPoint Un-verified.		17 Nov 2020 16:56:56
DataPoint Verified.		17 Nov 2020 16:56:50
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:57:32
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:03
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:09
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:11
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:26
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:29
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:24:52
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:33
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:35
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:20:39
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:51:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 9 (Day 9)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:50
User entered '13 Nov 2020'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:00
User entered '0'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:29:46
User entered '90'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:04
User entered '99.8' F	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:13
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:17
User entered 'Moderate (Moderate)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:41
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:45
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:49
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:09
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:13
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:17
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:19
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:22
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:32
User entered 'Moderate (Moderate)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:41
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:55
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:58
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:01
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:17
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:37:00

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 10 (Day 10)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:36:50
User entered '14 Nov 2020'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:36:54
User entered '0'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:36:58
User entered '94'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 12 Aug 2021 17:46:30**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:03
User entered '98.1' F	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:08
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:10
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:14
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:18
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:22
User entered 'Moderate (Moderate)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:25
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:29
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:34
User entered 'Moderate (Moderate)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:39
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:40
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:37:50
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:04
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:07
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:09
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:11
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:14
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:39:03



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 11 (Day 11)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:28
User entered '15 Nov 2020'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:33
User entered '0'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:38
User entered '97'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47
User entered '99.3' F	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:52
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:26
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:29
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:33
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:36
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:39
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:43
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:48
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:53
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:56
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:01
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:05
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:08
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:10
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:15
User entered 'None (None)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:42:20
User entered 'Mild (Mild)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 15:40:21

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 12 (Day 12)'	(b) (4) Jennifer Nagg (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:49
User entered '16 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:50
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:53
User entered '97'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:44:58
User entered '98.3' F	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:02
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:06
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:17
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:19
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:22
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:27
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:36
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:40
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:45
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:45:48
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:10
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:23
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:18
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:15
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:33
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:46:37
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 17:15:06

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 13 (Day 13)'	(b) (4) Jennifer Nagg (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:10:50
User entered '17 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:10:54
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:10:57
User entered '99'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:10:59
User entered '98.1' F	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:16
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:19
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:23
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:24
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:30
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:34
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:37
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:41
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:45
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:47
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:55
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:11:58
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:06
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:17
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:09
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:15
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:56:17

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 14 (Day 14)'	(b) (4) Emily Dougherty (b) (4)	19 Nov 2020 18:35:15
	(b) (4)	

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:06
User entered '18 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:08
User entered '0'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:03
User entered '98'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:04
User entered '97.6' F	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:14
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:16
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:17
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:19
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:20
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:22
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:32
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:35
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:38
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:41
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:46
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:51
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:56
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:28:59
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:29:00
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:29:02
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	19 Nov 2020 18:35:15



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 15 (Day 15)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:34
User entered '19 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:36
User entered '0'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:31
User entered '98'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:33
User entered '97.8' F	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:58
DataPoint Un-verified.		24 Nov 2020 21:53:56
DataPoint Verified.		24 Nov 2020 21:53:37
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:54:00
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:54
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:53:41
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:43
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:44
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:45
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:47
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:49
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:50
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:52
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:53
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:56
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:58
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:59
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:54:01
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:54:02
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:54:04
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:21:53

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 16 (Day 16)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:51:20
User entered '20 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:51:22
User entered '0'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:38
User entered '98'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (16)**

**Generated On: 12 Aug 2021 17:46:30**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:40
User entered '97.4' F	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:41
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:43
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:45
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:46
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:51
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:53
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:55
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:52:57
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:07
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:05
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:04
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:08
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:09
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:10
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:12
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:53:13
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:22:47

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 17 (Day 17)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:01
User entered '21 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:03
User entered '0'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:27
User entered '97'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:29
User entered '97.4' F	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:32
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:33
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:35
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:37
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:39
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:43
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:41
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:44
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:47
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:48
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:50
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:52
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:53
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:55
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:56
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:50:58
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:23:34

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 18 (Day 18)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:15
User entered '22 Nov 2020'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:16
User entered '0'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:18
User entered '98'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:19
User entered '97.5' F	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:21
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:22
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:24
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:26
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:27
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:29
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:30
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:31
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:33
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:38
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:37
User entered 'Mild (Mild)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:40
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:41
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:43
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:44
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:46
User entered 'None (None)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 17:24:25



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 19 (Day 19)'	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:07
User entered '23 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:09
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:11
User entered '99'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:12
User entered '97.3' F	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:21
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:22
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:24
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:28
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:30
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:32
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:33
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:37
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:41
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:43
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:48
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:52
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:54
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:56
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:48:58
User entered 'None (None)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:49:00
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 14:17:42

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 20 (Day 20)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '24 Nov 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:40
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

**US3802034**

**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (20)**

**Generated On: 12 Aug 2021 17:46:30**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:44
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.8' F	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:49
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:24:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:27
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:21
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:25:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	Jamie Fries (b) (4)	25 Nov 2020 19:46:55



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:25:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	Jamie Fries (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:25:16
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	Jamie Fries (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:15
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:25:11
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:46:55

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 21 (Day 21)'	Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '25 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:11
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.4' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:53
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:26:49
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	Dominic Kramer (b) (4)	01 Dec 2020 14:15:28



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Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:48
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

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Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:45
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:44
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

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Form: Symptom Log (21)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:28
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

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Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:39
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:37
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28



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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

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Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:26:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:15:28

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Form: Symptom Log (22)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 22 (Day 22)'	Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:27:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '26 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:27:32
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:27:34
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:17:01

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:27:37
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01



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Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:35
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

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Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:40
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01



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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:53
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

US3802034

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Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:59
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01

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Form: Symptom Log (22)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:32:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:17:01



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 23 (Day 23)'	Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '27 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:25
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:28
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

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**Folder: Covid-19 Assessment 05 Nov 2020**

**Form: Symptom Log (23)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:18:29

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Form: Symptom Log (23)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.4' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:34:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

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Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29



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Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:34:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:34:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:34:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:59
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:48
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:46
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:45
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:33:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:18:29

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 24 (Day 24)'	(b) (4) Dominic Kramer (b) (4)	01 Dec 2020 14:19:27

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:35:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '28 Nov 2020'	Dominic Kramer (b) (4)	01 Dec 2020 14:19:27



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Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:35:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:35:45
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:35:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:34
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:31
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:28
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:26
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:25
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:22
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:19
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:19:27

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 25 (Day 25)'	Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:36:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '29 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:20:30

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:19
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:53
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:37:59
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:10
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:12
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:38:13
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:20:30

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 26 (Day 26)'	Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:39:11
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User entered '26 Nov 2020'	Emily Dougherty (b) (4)	03 Dec 2020 18:43:05
	(b) (4)	
	Dominic Kramer (b) (4)	01 Dec 2020 14:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:13
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '99'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.5' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:25
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:27
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:53
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:57
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38



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Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:39:48
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:21:38



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 27 (Day 27)'	Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Form: Symptom Log (27)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '01 Dec 2020'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:44
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	03 Dec 2020 18:40:28

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Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:46
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.2' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	03 Dec 2020 18:40:28
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28



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Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:40:55
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	03 Dec 2020 18:40:28
	(b) (4)	

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:14
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Form: Symptom Log (27)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:16
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28



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Form: Symptom Log (27)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:39
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:47
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:45
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	03 Dec 2020 18:40:28
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:41:49
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:40:28

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 28 (Day 28)'	(b) (4) Jennifer Nagg (b) (4)	03 Dec 2020 18:44:40

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:42:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '2 Dec 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:42:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:42:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '99'	Jennifer Nagg (b) (4)	03 Dec 2020 18:44:40

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:42:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.4' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:42:49
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:02:36
User closed query 'Source states "none". please confirm. ' (Site from CRA).		17 Feb 2021 17:02:34
Query 'Source states "none". please confirm. ' answered with 'Updated ' (Site from CRA).	Emily Carney (b) (4)	12 Feb 2021 20:56:15
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	12 Feb 2021 20:56:07
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Emily Carney (b) (4)	12 Feb 2021 20:56:07
User opened query 'Source states "none". please confirm. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 12:43:49
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	03 Dec 2020 18:44:40
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:42:59
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40



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Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:06
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

Generated On: 12 Aug 2021 17:46:30

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:12
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:16
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Mild (Mild)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

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Form: Symptom Log (28)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:21
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

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Form: Symptom Log (28)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (28)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:43:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:44:40

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'Day 29 (Day 29)'	Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:35
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '03 Dec 2020'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '98'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13



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**Form: Symptom Log (29)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
User entered '%'	System	14 Dec 2020 19:43:13

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '97.2' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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Form: Symptom Log (29)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

US3802034

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Form: Symptom Log (29)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:44:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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Form: Symptom Log (29)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:45:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 17:46:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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Form: Symptom Log (29)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:06
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13



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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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Form: Symptom Log (29)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:10
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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Form: Symptom Log (29)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:11
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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Form: Symptom Log (29)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:13
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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Form: Symptom Log (29)

Generated On: 12 Aug 2021 17:46:30

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:15
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:17
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:19
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

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Form: Symptom Log (29)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:21
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 17:46:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	14 Dec 2020 19:43:13

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (29)

Generated On: 12 Aug 2021 17:46:30

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:09
DataPoint Verified.		10 Feb 2021 12:45:24
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'None (None)'	(b) (4)	
	Emily Dougherty (b) (4)	14 Dec 2020 19:43:13
	(b) (4)	

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). DataPoint Verified.		18 Nov 2020 04:35:50
		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'done' (Site from System).	Jennifer Nagg (b) (4)	09 Nov 2020 14:51:05
	(b) (4)	
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	09 Nov 2020 14:48:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	09 Nov 2020 14:48:51
	(b) (4)	
User entered 'No (N)'	Jennifer Nagg (b) (4)	05 Nov 2020 16:30:09
	(b) (4)	

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Jennifer Nagg (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[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)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
DataPoint Verified.		17 Nov 2020 16:13:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 17:46:30

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:15
User entered '1'	System	09 Nov 2020 14:48:51
User entered '0'	System	05 Nov 2020 16:30:09

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:13
User closed query 'Please reconcile as symptom log on 13Nov2020 notes O2 of 90%' (Site from CRA).		20 Nov 2020 21:27:11
Query 'Please reconcile as symptom log on 13Nov2020 notes O2 of 90%' answered with 'entered 11/13/2020 90%' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 21:20:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	20 Nov 2020 21:20:28
User opened query 'Please reconcile as symptom log on 13Nov2020 notes O2 of 90%' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 21:14:29
DataPoint Un-verified.		20 Nov 2020 21:13:51
Query 'Please reconcile as symptom log on 13Nov2020 notes O2 of 90%' canceled (Site from CRA).		20 Nov 2020 21:13:03
User opened query 'Please reconcile as symptom log on 13Nov2020 notes O2 of 90%' (Site from CRA).		18 Nov 2020 05:26:20
DataPoint Verified.		17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:16
DataPoint Un-verified.	Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:26
DataPoint Un-verified.		20 Nov 2020 21:27:21
DataPoint Verified.		20 Nov 2020 21:27:19
DataPoint Un-verified.	Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:23
DataPoint Un-verified.	Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
User entered '90' reason for change: Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	20 Nov 2020 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).		19 Feb 2021 03:33:34
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:49
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 05:27:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
DataPoint Verified.		05 Mar 2021 14:58:26
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
DataPoint Un-verified.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
Signature has been broken.	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User entered empty; reason for change Data Entry Error	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
DataPoint Verified.		05 Mar 2021 14:58:30
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
DataPoint Un-verified.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
Signature has been broken.	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User entered empty; reason for change Data Entry Error	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
DataPoint Verified.		08 Apr 2021 14:41:41
DataPoint Un-verified.		03 Mar 2021 04:37:42
DataPoint Verified.		03 Mar 2021 04:37:40
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
DataPoint Un-verified.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
Signature has been broken.	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User entered empty; reason for change Data Entry Error	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
DataPoint Verified.		05 Mar 2021 14:58:49
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
DataPoint Un-verified.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
Signature has been broken.	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User entered empty; reason for change Data Entry Error	Melissa Andrasko (b) (4)	15 Feb 2021 16:35:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

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Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12



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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 17:46:30

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:20
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:25:42
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:23:12

US3802034

Folder: Covid-19 Assessment 05 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 17:46:30

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:11:24
User signature succeeded.	Judith Martin (b) (4)	29 Mar 2021 12:30:43
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	26 Mar 2021 19:19:18
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	26 Mar 2021 19:19:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	26 Mar 2021 19:19:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 12:46:43
User signature succeeded.	Judith Martin (b) (4)	29 Jan 2021 19:42:47
	(b) (4)	
Signature has been broken.	Emily Dougherty (b) (4)	28 Jan 2021 21:04:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	28 Jan 2021 21:04:19
	(b) (4)	
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered 'No (N)'	Jennifer Nagg (b) (4)	10 Dec 2020 21:05:55
	(b) (4)	



**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 3 (Day 3)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered '7 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 5 (Day 5)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered '9 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 7 (Day 7)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 17:46:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06



**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered '11 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 9 (Day 9)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 17:46:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 for Day 14 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please complete, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 05:33:12
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 for Day 14 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please complete, thank you.' answered with 'entered' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	17 Dec 2020 20:22:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 for Day 14 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:05:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:18:33
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:08:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 20:08:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 20:08:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 16:26:06
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered '13 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	13 Nov 2020 20:08:13
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 14 (Day 14)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 17:46:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
DataPoint Verified.		03 Mar 2021 04:45:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:22:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:22:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 07:08:06
		17 Nov 2020 16:18:33
Query 'Data is required. Please complete.' answered with 'not due yet' (Site from System).	Jennifer Nagg (b) (4)	15 Nov 2020 12:34:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 16:26:06
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 16:26:06
	(b) (4)	

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
DataPoint Verified.		03 Mar 2021 04:45:06
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:22:01
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:22:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 16:26:06
	(b) (4)	

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 21 (Day 21)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06



US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 17:46:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
DataPoint Verified.		03 Mar 2021 04:45:19
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 for day 21 reported in PPD central lab , however sample details are missing in EDC. Please complete.' (Site from DM).		01 Feb 2021 07:50:45
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 for day 21 reported in PPD central lab , however sample details are missing in EDC. Please complete.' answered with 'Data entry error' (Site from DM).	Dominic Kramer (b) (4) (b) (4)	25 Jan 2021 14:56:02
DataPoint Un-verified.	Dominic Kramer (b) (4) (b) (4)	25 Jan 2021 14:55:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Dominic Kramer (b) (4) (b) (4)	25 Jan 2021 14:55:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 for day 21 reported in PPD central lab , however sample details are missing in EDC. Please complete.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:17:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 07:08:10
DataPoint Verified.		17 Nov 2020 16:18:33
Query 'Data is required. Please complete.' answered with 'not due yet' (Site from System).	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 12:34:33
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 16:26:06
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 25NOV2020 for Day 21 is recorded in EDC, however sample is reported with 26NOV2020 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).		01 Apr 2021 04:53:10
Query 'Per GCL Lab Recon: Saliva: Sample dated 25NOV2020 for Day 21 is recorded in EDC, however sample is reported with 26NOV2020 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'Correct date is 25Nov2020. Will check with PPD regarding samples' (Site from DM). DataPoint Verified.	Emily Dougherty (b) (4) (b) (4)	31 Mar 2021 19:52:33
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 25NOV2020 for Day 21 is recorded in EDC, however sample is reported with 26NOV2020 for Day 21 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:45:23
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered '25 Nov 2020' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	26 Jan 2021 14:55:38
DataPoint Un-verified.	Dominic Kramer (b) (4) (b) (4)	25 Jan 2021 14:55:54
User entered '26 Nov 2020' reason for change: Data Entry Error	Dominic Kramer (b) (4) (b) (4)	25 Jan 2021 14:55:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:18:33
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

**US3802034**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
User accepted default value 'Day 28 (Day 28)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:26:06

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 17:46:30

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
DataPoint Verified.		15 Apr 2021 21:35:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:20:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	17 Dec 2020 20:20:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 07:08:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:18:33
Query 'Data is required. Please complete.' answered with 'not due yet' (Site from System).	Jennifer Nagg (b) (4)	15 Nov 2020 12:34:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 16:26:06
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 16:26:06
	(b) (4)	

US3802034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:50
DataPoint Verified.		15 Apr 2021 21:35:09
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 04DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Recon: Saliva: Samples dated 04DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' answered with 'illness visit is correct' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:21:34
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 04DEC2020 is reported under Illness Visit Day 28 in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' (Site from DM).	Jennifer Nagg (b) (4)	10 Jan 2021 11:24:28
DataPoint Un-verified.	(b) (4)	
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 05:14:28
DataPoint Verified.	Jennifer Nagg (b) (4)	17 Dec 2020 20:20:55
User entered empty.	Jennifer Nagg (b) (4)	17 Dec 2020 20:20:55
	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 16:18:33
	Jennifer Nagg (b) (4)	13 Nov 2020 16:26:06
	(b) (4)	

US3802034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:51
DataPoint Verified.		17 Nov 2020 17:44:13
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:31:14

US3802034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Unscheduled in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).		18 Dec 2020 05:32:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Unscheduled in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with '12/4 was day 28, entered' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	17 Dec 2020 20:26:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04DEC2020 is reported under Unscheduled in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:44:15
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).		15 Nov 2020 21:10:34
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'done' (Site from CRA).	Jennifer Nagg (b) (4) (b) (4)	15 Nov 2020 12:35:04
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 16:30:08
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:31:14

US3802034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 06:51:51
DataPoint Verified.		17 Nov 2020 17:44:17
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:31:14



US3802034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:51:51
User entered 'SICKD1'	System	05 Nov 2020 16:31:14

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:44:53
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:44:59
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:02
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '11:04'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

**US3802034**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
User entered '5 Nov 2020 11:04'	System	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:06
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered missing code ND - Not Done.	(b) (4) Jennifer Nagg (b) (4)	05 Nov 2020 16:32:47
DataPoint set to visible.	(b) (4) System	05 Nov 2020 16:31:14

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:07
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered missing code ND - Not Done.	(b) (4) Jennifer Nagg (b) (4)	05 Nov 2020 16:32:47
DataPoint set to visible.	(b) (4) System	05 Nov 2020 16:31:14

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:12
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '98.5' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47



US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:15
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Other (Other)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:17
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'infrared'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:22
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '79'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

**US3802034**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
User entered 'bpm'	System	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '22'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
User entered 'breaths/min'	System	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:28
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '135'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
User entered 'mmHg'	System	05 Nov 2020 16:32:47



US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
DataPoint Verified.		17 Nov 2020 17:45:30
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '85'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01
User entered 'mmHg'	System	05 Nov 2020 16:32:47

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01

US3802034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:01

US3802034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:23
DataPoint Verified.		17 Nov 2020 17:45:56
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:59

US3802034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:23
DataPoint Verified.		17 Nov 2020 17:45:58
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:32:59

US3802034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 17:46:30

[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 06:52:33
DataPoint Verified.		17 Nov 2020 17:46:18
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:33:10

US3802034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:33
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 for Day 21 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' (Site from DM).		01 Feb 2021 07:50:21
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 for Day 21 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' answered with 'sample was collected on 25nov2020. updated in saliva log' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	26 Jan 2021 14:56:16
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 for Day 21 if yes, please update the sample details in Saliva log as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 06:15:05
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 if yes, please update the sample details in Saliva log as per CCGs Version 2.0 page 16 & 45 as its reported in PPD central lab.' (Site from DM).		25 Jan 2021 06:15:05
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 if yes, please update the sample details in Saliva log as per CCGs Version 2.0 page 16 & 45 as its reported in PPD central lab.' answered with 'The date listed for the blood sample is correct 05NOV2020. The query mentions saliva collection but this is not the place for saliva collection.' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 15:13:20
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for the response, however please confirm if sample was collected on 26NOV2020 if yes, please update the sample details in Saliva log as per CCGs Version 2.0 page 16 & 45 as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:06:10

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3802034

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:06:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with '11/5/2020 is correct' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	10 Jan 2021 11:29:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:43:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:46:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	05 Nov 2020 16:33:10

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:45
DataPoint Verified.		10 Feb 2021 13:00:19
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:02:00

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:45
DataPoint Verified.		10 Feb 2021 13:00:21
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '4 Dec 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:02:00

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 06:52:45
DataPoint Verified.		10 Feb 2021 13:00:23
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:02:00

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:45
User entered 'SICKD28'	System	04 Dec 2020 15:02:00

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:44
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '4 Dec 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:46
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '09:05'	(b) (4)	
	Jennifer Nagg (b) (4)	04 Dec 2020 15:06:06
	(b) (4)	



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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
User entered '4 Dec 2020 09:05'	System	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:48
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered missing code ND - Not Done.	(b) (4) Jennifer Nagg (b) (4)	04 Dec 2020 15:06:06
DataPoint set to visible.	(b) (4) System	04 Dec 2020 15:02:00

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered missing code ND - Not Done.	(b) (4) Jennifer Nagg (b) (4)	04 Dec 2020 15:06:06
DataPoint set to visible.	(b) (4) System	04 Dec 2020 15:02:00

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:53
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '97.4' F	Jennifer Nagg (b) (4)	04 Dec 2020 15:06:06
	(b) (4)	

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:55
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Other (Other)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:00:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'infrared'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:01:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '86'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
User entered 'bpm'	System	04 Dec 2020 15:06:06



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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:01:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '18'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
User entered 'breaths/min'	System	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:01:06
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '152'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
User entered 'mmHg'	System	04 Dec 2020 15:06:06

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
DataPoint Verified.		05 Mar 2021 15:01:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '82'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52
User entered 'mmHg'	System	04 Dec 2020 15:06:06

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:52:52



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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:16
DataPoint Verified.		03 Mar 2021 04:43:43
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:12

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:16
DataPoint Verified.		03 Mar 2021 04:43:45
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:12

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 17:46:30

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 06:53:21
DataPoint Verified.		15 Apr 2021 21:40:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.' answered with 'Participant was seen 04Dec2020. Kit Type UV was used to collect the specimens. It was logged in as an unscheduled visit in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 14:31:22
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.'	Lalicia Roman (b) (4)	22 Jan 2021 14:56:31
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.'	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in EDC, however the same SARS-CoV-2 serum sample is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:23:23
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	04 Dec 2020 15:06:22
	(b) (4)	

US3802034

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 17:46:30

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:21
DataPoint Verified.		15 Apr 2021 21:40:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '4 Dec 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	04 Dec 2020 15:06:22

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:44:35
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:29:03
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:44:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:29:03

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 21:38:39
DataPoint Verified.		22 Feb 2021 20:44:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Clinic (Clinic)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:29:03

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 18:29:03



US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:47:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '6 Jan 2021'	Matthew Lee (b) (4)	06 Jan 2021 18:29:19
	(b) (4)	

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 17:46:30**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:33:33
User entered '0'	(b) (4) Emily Carney (b) (4)	08 Apr 2021 14:38:12
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:32:25

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:47:32
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User closed query 'Per CDM, per Sponsor Review: 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).		16 Apr 2021 01:09:54
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:33:33
Query 'Per CDM, per Sponsor Review: 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).	(b) (4) Emily Carney (b) (4)	08 Apr 2021 14:38:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	Emily Carney (b) (4)	08 Apr 2021 14:38:12
User opened query 'Per CDM, per Sponsor Review: 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 10:31:56
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:32:25

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:47:34
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021'	(b) (4) Matthew Lee (b) (4)	06 Jan 2021 18:29:19

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:47:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Placebo (Placebo)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	
	System	20 Jan 2021 12:52:46
User entered 'Placebo (Placebo)'	Matthew Lee (b) (4)	06 Jan 2021 18:29:19
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	
	System	20 Jan 2021 12:52:46
User entered 'Placebo (Placebo)'	Matthew Lee (b) (4)	06 Jan 2021 18:29:19
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4)	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 17:46:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '1'	System	06 Jan 2021 18:29:19

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'I'	System	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '155.2' cm	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:31
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '159' lb	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '30.00482'	System	06 Jan 2021 18:30:23
DataPoint set to visible.	System	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '155.2' cm	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:31
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '159' lb	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '30.00482'	System	06 Jan 2021 18:30:23
DataPoint set to visible.	System	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:51
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:54
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '12:15'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '6 Jan 2021 12:15'	System	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '98.5' F	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:58:01
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 18:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 18:32:43
User entered 'Other (Other)' reason for change: Data Matthew Lee Entry Error	(b) (4)	06 Jan 2021 18:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:58:04
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered 'Infrared' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:32:43
	(b) (4)	
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:07:56
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 18:32:43
data change (Site from System).		06 Jan 2021 18:32:43
User entered '80' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:32:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 18:30:23
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'bpm'	System	06 Jan 2021 18:32:43
User entered empty.	System	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:07:59
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 18:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 18:32:43
User entered '18' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:32:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'breaths/min'	System	06 Jan 2021 18:32:43
User entered empty.	System	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 18:32:43
data change (Site from System).		06 Jan 2021 18:32:43
User entered '138' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:32:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 18:30:23
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	06 Jan 2021 18:32:43
User entered empty.	System	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 18:32:43
data change (Site from System).		06 Jan 2021 18:32:43
User entered '89' reason for change: Data Entry	Matthew Lee (b) (4)	06 Jan 2021 18:32:43
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	06 Jan 2021 18:32:43
User entered empty.	System	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '155.2' cm	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 20:57:31
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '159' lb	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 17:46:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '30.00482'	System	06 Jan 2021 18:30:23
DataPoint set to visible.	System	06 Jan 2021 18:29:19

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:41
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:43
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '6 Jan 2021'	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:46
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:31:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Jan 2021 18:31:56
User entered '13:25' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	



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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '6 Jan 2021 13:25'	System	06 Jan 2021 18:31:56
User entered empty.	System	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:31:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Jan 2021 18:31:56
User entered '98.9' F reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
User entered empty.	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:08:58
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered 'Infrared' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
	(b) (4)	
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 21:09:00
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 18:31:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 18:31:56
User entered '74' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'bpm'	System	06 Jan 2021 18:31:56
User entered empty.	System	06 Jan 2021 18:30:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 18:31:56
data change (Site from System).		06 Jan 2021 18:31:56
User entered '16' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 18:30:23
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'breaths/min'	System	06 Jan 2021 18:31:56
User entered empty.	System	06 Jan 2021 18:30:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:06
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:31:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Jan 2021 18:31:56
User entered '138' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Jan 2021 18:30:23
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	06 Jan 2021 18:31:56
User entered empty.	System	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:08
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 18:31:56
data change (Site from System).		06 Jan 2021 18:31:56
User entered '80' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:31:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 18:30:23
	Matthew Lee (b) (4)	06 Jan 2021 18:30:23
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	06 Jan 2021 18:31:56
User entered empty.	System	06 Jan 2021 18:30:23

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:32
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:32:59

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 21:09:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021'	Matthew Lee (b) (4)	06 Jan 2021 18:32:59

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:48
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	06 Jan 2021 18:33:30
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	06 Jan 2021 18:33:30
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	06 Jan 2021 18:33:12
User entered 'Yes (Y)'	Matthew Lee (b) (4)	06 Jan 2021 18:33:12

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:50
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:33:12
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

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)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:52
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:33:12

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mRNA-1273'	System	06 Jan 2021 18:33:12
DataPoint set to visible.	System	06 Jan 2021 18:29:19

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:09:54
User signature succeeded.	Judith Martin (b) (4) (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021' reason for change: Data Entry Error	Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:33:30
User entered empty.	Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:33:12

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:10:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '12:55' reason for change: Data Entry Error	Matthew Lee (b) (4)	06 Jan 2021 18:33:30
	(b) (4)	
User entered empty.	Matthew Lee (b) (4)	06 Jan 2021 18:33:12
	(b) (4)	

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 17:46:30**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '6 Jan 2021 12:55'	System	06 Jan 2021 18:33:30
User entered empty.	System	06 Jan 2021 18:33:12

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:10:07
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Matthew Lee (b) (4)	06 Jan 2021 18:33:12
	(b) (4)	

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:10:10
User entered 'ONCE'	System	06 Jan 2021 18:33:12

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 18:33:12



US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:02
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:15

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:03
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:25:32
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).		13 Jan 2021 19:31:51
User entered '6 Jan 2021'	Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:15

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:05
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '12:34'	(b) (4)	
	Matthew Lee (b) (4)	06 Jan 2021 18:34:15
	(b) (4)	

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '6 Jan 2021 12:34'	System	06 Jan 2021 18:34:15

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:30
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:38

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:32
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '6 Jan 2021'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:38

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 17:46:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:33
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '12:37'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:38

**US3802034**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 17:46:30**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '6 Jan 2021 12:37'	System	06 Jan 2021 18:34:38



US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
DataPoint Verified.		22 Feb 2021 21:11:38
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Matthew Lee (b) (4) (b) (4)	06 Jan 2021 18:34:57

US3802034

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'I'	System	06 Jan 2021 18:34:57

**US3802034**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:44:51

US3802034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '13 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:44:51

US3802034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:44:51

US3802034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered empty.	(b) (4) Emily Carney (b) (4)	13 Jan 2021 18:44:51
	(b) (4)	

US3802034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
DataPoint Verified.		23 Apr 2021 00:55:18
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	13 Jan 2021 18:44:56
	(b) (4)	

**US3802034**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User entered 'I'	System	13 Jan 2021 18:44:56



**US3802034**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:23:29
User entered 'I'	System	13 Jan 2021 18:44:56
DataPoint set to visible.	System	13 Jan 2021 18:44:56

US3802034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:09

US3802034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '3 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:09

US3802034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[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 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Clinic (Clinic)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:09

**US3802034**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'OLD29'	System	03 Feb 2021 19:26:09

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '3 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52



**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 17:46:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '11:40'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '3 Feb 2021 11:40'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '97.2' F	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Other (Other)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Infrared'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '58'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'bpm'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '16'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52



US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'breaths/min'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '154'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '87'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '3 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52



**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '12:29'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '3 Feb 2021 12:29'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '97.3' F	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered 'Other (Other)'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Infrared'	(b) (4) Emily Carney (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '67'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

**US3802034**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'bpm'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '16'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52



US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'breaths/min'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '142'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '84'	Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mmHg'	System	03 Feb 2021 19:27:52

US3802034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:16

US3802034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4)	03 Feb 2021 19:26:16
	(b) (4)	

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40



US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

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)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'mRNA-1273'	System	03 Feb 2021 19:26:40
DataPoint set to visible.	System	13 Jan 2021 18:44:56

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '3 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '11:52'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered '3 Feb 2021 11:52'	System	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Carney (b) (4) (b) (4)	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'ONCE'	System	03 Feb 2021 19:26:40



US3802034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 17:46:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 19:26:40

US3802034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	03 Feb 2021 19:26:45

**US3802034**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:38:39
User entered 'I'	System	03 Feb 2021 19:26:45

**US3802034**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	10 Feb 2021 15:38:17

US3802034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '10 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	10 Feb 2021 15:38:17

US3802034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 17:46:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4)	10 Feb 2021 15:38:17

**US3802034**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 17:46:30**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4)	10 Feb 2021 15:38:17

US3802034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 17:46:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
DataPoint Verified.		23 Apr 2021 00:55:31
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4)	
	Emily Carney (b) (4)	10 Feb 2021 15:38:21
	(b) (4)	



**US3802034**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 17:46:30**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:09:36
User entered 'I'	System	10 Feb 2021 15:38:21

US3802034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:36:07

US3802034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User closed query 'Per CDM : Please note Visit 4 Day 209 and OL-D57 having same dates ( 17 Mar 2021). Kindly review and reconcile. else clarify. Thank You ' (Site from DM).		29 Mar 2021 15:19:00
Query 'Per CDM : Please note Visit 4 Day 209 and OL-D57 having same dates ( 17 Mar 2021). Kindly review and reconcile. else clarify. Thank You ' answered with 'Confirm visits conducted together.' (Site from DM).	Emily Carney (b) (4) (b) (4)	29 Mar 2021 12:40:29
User opened query 'Per CDM : Please note Visit 4 Day 209 and OL-D57 having same dates ( 17 Mar 2021). Kindly review and reconcile. else clarify. Thank You ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:53:20
User signature succeeded.	Judith Martin (b) (4) (b) (4)	22 Mar 2021 15:55:04
User entered '17 Mar 2021'	Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:36:07

US3802034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 17:46:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:36:07

**US3802034**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 17:46:30**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered 'OLD57'	System	17 Mar 2021 13:36:07

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	17 Mar 2021 13:36:54

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '17 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54
	(b) (4)	

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '09:10'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54
	(b) (4)	



**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered '17 Mar 2021 09:10'	System	17 Mar 2021 13:36:54

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '97.9' F	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54
	(b) (4)	

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54
	(b) (4)	

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '66'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered 'bpm'	System	17 Mar 2021 13:36:54

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '18'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered 'breaths/min'	System	17 Mar 2021 13:36:54



US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '133'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54
	(b) (4)	

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered 'mmHg'	System	17 Mar 2021 13:36:54

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '83'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:36:54

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered 'mmHg'	System	17 Mar 2021 13:36:54

US3802034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 17:46:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56

**US3802034**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 17:46:30**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56

US3802034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:37:01
	(b) (4)	

US3802034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 17:46:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered empty.	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:37:01
	(b) (4)	



US3802034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:37:14

US3802034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 17:46:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '17 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:37:14
	(b) (4)	

**US3802034**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 17:46:30**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User signature succeeded.	Judith Martin (b) (4)	22 Mar 2021 15:55:04
User entered '09:22'	(b) (4) Lalicia Roman (b) (4)	17 Mar 2021 13:37:14
	(b) (4)	

**US3802034**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 17:46:30**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:57:56
User entered '17 Mar 2021 09:22'	System	17 Mar 2021 13:37:14

US3802034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 17:46:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:31:28
DataPoint Verified.		17 Nov 2020 19:12:16
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 14:49:10

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:47:03
Reviewed for Safety.		10 Nov 2020 17:13:48
User entered 'USA-US098-2020-mRNA-1273-P301000003'	System	10 Nov 2020 17:13:29
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 17:13:29

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 01:31:21
User closed query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCg Page 35-36). Thank you.' (Site from DM).		22 Nov 2020 22:05:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:36:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:36:01
Data point term sent to Coder	System	20 Nov 2020 16:03:58
Query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCg Page 35-36). Thank you.' answered with 'updated' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:03:56
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:03:42
Coding entries removed.	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:03:42
Signature has been broken.	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:03:42
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:03:42
User opened query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCg Page 35-36). Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:20:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:05
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:51:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Nov 2020 14:51:32
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 14:51:01
User entered 'COVID 19'	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:47:07
Signature has been broken.	Jennifer Nagg (b) (4)	13 Nov 2020 16:22:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	13 Nov 2020 16:22:04
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4)	
	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:10
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'No (N)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:11
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:15
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '5 Nov 2020'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

**US3802034**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:17
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:27:41
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:21
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:27:46
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	Jennifer Nagg (b) (4)	10 Jan 2021 10:57:46
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'participant is still symptomatic' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 20:29:24
DataPoint Verified.	Lalicia Roman (b) (4)	20 Nov 2020 16:04:24
	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 19:13:45
DataPoint Un-verified.		17 Nov 2020 19:13:18
DataPoint Verified.		17 Nov 2020 17:47:27
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).		16 Nov 2020 19:19:03
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered empty.	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:29
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:44:42
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).		07 Dec 2020 20:41:04
User entered empty.	System	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:31:28
User closed query 'Severity is not recorded in AE log in source. please confirm origin of data. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:31:27
Query 'Severity is not recorded in AE log in source. please confirm origin of data. ' answered with 'located in source' (Site from CRA).	Lalicia Roman (b) (4) (b) (4)	20 Nov 2020 16:14:00
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:30
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User opened query 'Severity is not recorded in AE log in source. please confirm origin of data. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:49:01
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:38
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 14:50:33
User entered 'No (N)' reason for change: Data Entry Error	System	09 Nov 2020 14:50:33
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:33
User entered empty.	(b) (4)	
	System	09 Nov 2020 14:50:21
	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

**US3802034**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21



US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

**US3802034**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:54
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21

US3802034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:47:57
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:51:25
Signature has been broken.	Jennifer Nagg (b) (4)	13 Nov 2020 16:24:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	Jennifer Nagg (b) (4)	13 Nov 2020 16:24:13
User signature succeeded.	(b) (4)	
	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered 'None (NONE)'	(b) (4)	
	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 04:27:52
DataPoint Un-verified.	Emily Carney (b) (4)	25 Feb 2021 13:18:49
Signature has been broken.	(b) (4) Emily Carney (b) (4)	25 Feb 2021 13:18:49
User entered '0' reason for change: Data Entry Error	(b) (4) Emily Carney (b) (4)	25 Feb 2021 13:18:49
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
Signature has been broken.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 14:59:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '1'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 17:46:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 04:27:54
DataPoint Un-verified.	Emily Carney (b) (4)	25 Feb 2021 13:18:49
Signature has been broken.	(b) (4) Emily Carney (b) (4)	25 Feb 2021 13:18:49
User entered '1' reason for change: Data Entry Error	(b) (4) Emily Carney (b) (4)	25 Feb 2021 13:18:49
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
Signature has been broken.	(b) (4) Melissa Andrasko (b) (4)	15 Feb 2021 14:59:59
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered '0'	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:42:54
	(b) (4)	
Signature has been broken.	Melissa Andrasko (b) (4)	15 Feb 2021 15:00:39
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	
User entered '0'	Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:27:56
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:47:04
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'entered' (Site from Safety).	Jennifer Nagg (b) (4) (b) (4)	10 Jan 2021 11:00:38
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	10 Jan 2021 10:57:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jennifer Nagg (b) (4) (b) (4)	10 Jan 2021 10:57:46
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:31:32
DataPoint Un-verified.	Melissa Andrasko (b) (4)	23 Nov 2020 21:17:10
Signature has been broken.	Melissa Andrasko (b) (4)	23 Nov 2020 21:17:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Melissa Andrasko (b) (4)	23 Nov 2020 21:17:10
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:06
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		16 Nov 2020 19:19:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Nov 2020 10:24:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Nagg (b) (4) (b) (4)	09 Nov 2020 14:50:21

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	09 Nov 2020 14:50:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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)	11 Jan 2021 17:47:08
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 'no treatment provided' (Site from Safety).	Jennifer Nagg (b) (4)	10 Jan 2021 11:01:05
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' canceled (Site from Safety).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:55:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 02:15:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:40
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:51:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:19:47
User signature succeeded.	Judith Martin (b) (4)	16 Nov 2020 19:19:35
User entered empty.	(b) (4)	
	Jennifer Nagg (b) (4)	10 Nov 2020 10:24:42
	(b) (4)	(b) (4)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 14:50:33



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 16:22:04
User entered '0'	System	09 Nov 2020 14:50:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:34:48
Data point term sent to Coder	System	18 Nov 2020 19:34:26
User entered 'Tooth Infection'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:38
User entered 'No (N)'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:40:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:40:51
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:40:51
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:36
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:45
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:40:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:40:51
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:40:51
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:36
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
DataPoint Verified.		27 Apr 2021 09:28:18
User closed query 'The query is replied without any change. If Source mentions Start date as UN OCT2020, verify and reconcile. ' (Site from CRA). Query 'The query is replied without any change. If Source mentions Start date as UN OCT2020, verify and reconcile. ' answered with 'Source has OCT 29 2020 as start date, nothing to reconcile' (Site from CRA).	Melissa Andrasko (b) (4)	22 Apr 2021 18:59:53
User opened query 'The query is replied without any change. If Source mentions Start date as UN OCT2020, verify and reconcile. ' (Site from CRA). User closed query 'Data in Rave is still 29oct2020, please update to UNK Oct 2020. thank you ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:44:16
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	System	10 Jan 2021 11:04:20
Query 'Data in Rave is still 29oct2020, please update to UNK Oct 2020. thank you ' answered with 'done' (Site from CRA).	Jennifer Nagg (b) (4)	10 Jan 2021 11:04:20
	(b) (4)	10 Jan 2021 11:04:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Jan 2021 11:03:57
User entered 'UN Oct 2020' (non-conformant).	Jennifer Nagg (b) (4)	10 Jan 2021 11:03:57
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 15:40:32
User entered '29 Oct 2020' reason for change: Data Entry Error	Jamie Fries (b) (4)	21 Dec 2020 15:40:32
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 15:40:10
User entered 'UN Oct 2020' (non-conformant).	Jamie Fries (b) (4)	21 Dec 2020 15:40:10
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Data in Rave is still 29oct2020, please update to UNK Oct 2020. thank you ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:47:44
User closed query 'date in source is UNK Oct 2020, please verify ' (Site from CRA).		24 Nov 2020 17:47:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 13:58:59
User entered '29 Oct 2020' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	24 Nov 2020 13:58:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 13:57:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 13:57:37
User entered ' Oct 2020' (non-conformant).	Lalicia Roman (b) (4) (b) (4)	24 Nov 2020 13:57:37
Query 'date in source is UNK Oct 2020, please verify ' answered with 'updated' (Site from CRA).	Lalicia Roman (b) (4) (b) (4)	24 Nov 2020 13:56:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 13:56:26
User entered 'un Oct 2020' (non-conformant).	Lalicia Roman (b) (4) (b) (4)	24 Nov 2020 13:56:26
User opened query 'date in source is UNK Oct 2020, please verify ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 21:10:27
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:44:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:44:01
User entered '29 Oct 2020' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:44:01
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:36
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:48
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User entered empty.	System	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
DataPoint Verified.		27 Apr 2021 09:28:23
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Un-verified.	(b) (4) Jamie Fries (b) (4)	21 Dec 2020 15:39:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jamie Fries (b) (4)	21 Dec 2020 15:39:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:08:53
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:40:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:40:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:40:51
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:33:36
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
DataPoint Verified.		27 Apr 2021 09:28:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Jan 2021 11:03:57
User entered '31 Oct 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	10 Jan 2021 11:03:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 15:41:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 15:41:01
User entered '31 Oct 20' (non-conformant).	Jamie Fries (b) (4)	21 Dec 2020 15:41:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 15:39:29
DataPoint Un-verified.	Jamie Fries (b) (4)	21 Dec 2020 15:39:29
User entered '21 Oct 20' (non-conformant).	(b) (4)	
User entered '21 Oct 20' (non-conformant).	Jamie Fries (b) (4)	21 Dec 2020 15:39:29
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:09:01
User entered empty.	Emily Dougherty (b) (4)	18 Nov 2020 19:33:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 17:46:30**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:03
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User entered empty.	System	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:08
User entered 'No (N)'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36



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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:25
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:27
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:29
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:34
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:36
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:37
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:40
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:42
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:43
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:45
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:40:51
User entered 'Related (RELATED)'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:40:51
User entered 'Related (RELATED)'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:49
User entered 'Not Applicable (NOT APPLICABLE)'	Emily Carney (b) (4)	18 Nov 2020 19:40:51
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Emily Dougherty (b) (4)	18 Nov 2020 19:33:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:50
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:52
User entered 'I'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:53
User entered '0'	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 09:28:38
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Un-verified.	Jamie Fries (b) (4)	21 Dec 2020 15:39:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jamie Fries (b) (4)	21 Dec 2020 15:39:29
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:09:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Emily Dougherty (b) (4)	18 Nov 2020 19:33:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:56
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:09:58
User entered empty.	Emily Dougherty (b) (4) (b) (4)	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User entered '0'	System	18 Nov 2020 19:33:36

US3802034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 17:46:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53
User entered '0'	System	18 Nov 2020 19:33:36

**US3802034**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 17:46:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:53:32
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:16:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:53:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 19:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:19:43
Data point term sent to Coder	System	25 Aug 2020 19:18:00
User entered 'Hydrochlorothiazide'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:06
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:09
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		11 Nov 2020 17:11:53
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	19 Oct 2020 19:29:20
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:46:13
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'hypertension'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	18 Nov 2020 19:29:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 17:54:38
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
Signature has been broken.	(b) (4)	
	Jennifer Nagg (b) (4)	09 Nov 2020 16:14:47
User signature succeeded.	(b) (4)	
	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '25'	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:17:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:39
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'mg (mg)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:44
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:17:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:46
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'once daily (QD)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:51
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:53
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Oral (ORAL)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:54:56
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 10:44:00 17 Nov 2020 17:55:01
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated MH to match source of 2010 start date' (Site from DM). User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). User signature succeeded.	Jennifer Nagg (b) (4) (b) (4) (b) (4), (b) (6)	13 Nov 2020 20:01:31 11 Nov 2020 17:12:05 10 Nov 2020 10:24:42
Signature has been broken.	(b) (4) Melissa Andrasko (b) (4)	19 Oct 2020 19:29:10
User entered 'UN UNK 2010' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	19 Oct 2020 19:29:10
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2020'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:55:04
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:55:06
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:55:08
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 17:55:09
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:17:34

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	25 Aug 2020 19:17:34

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	25 Aug 2020 19:17:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 17:46:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '804 (804)'	System	25 Aug 2020 19:17:34

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:02:16
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 19:23:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:23:39
Data point term sent to Coder	System	25 Aug 2020 19:23:16
User entered 'Vitamin D3'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 04:53:33
User closed query 'Per CDM: Per CCGs, please verify data and consider updating 'Prophylaxis' to 'Yes' since Indication = Supplement. Thank you.' (Site from DM).		01 Mar 2021 16:12:35
Query 'Per CDM: Per CCGs, please verify data and consider updating 'Prophylaxis' to 'Yes' since Indication = Supplement. Thank you.' answered with 'updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	25 Feb 2021 21:18:08
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	25 Feb 2021 21:17:37
Signature has been broken.	Emily Carney (b) (4) (b) (4)	25 Feb 2021 21:17:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	25 Feb 2021 21:17:37
User opened query 'Per CDM: Per CCGs, please verify data and consider updating 'Prophylaxis' to 'Yes' since Indication = Supplement. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:04:44
DataPoint Verified.		17 Nov 2020 18:02:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:02:21
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'supplement'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:08
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '5000'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:32
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'IU (IU)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:35
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:22:20
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:43
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'once daily (QD)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:48
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:22:20
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:55
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Oral (ORAL)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:04:59
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:05:01
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2000'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:05:04
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:05:22
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:05:24
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:22:20
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:05:26
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:22:20



US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	25 Aug 2020 19:22:20

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	25 Aug 2020 19:22:20

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '804 (804)'	System	25 Aug 2020 19:22:20

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:17:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:17:53
Data point term sent to Coder	System	10 Feb 2021 18:09:45
Query 'CDM-Coding: This medication can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:08:55
' canceled (Site from System).		
User opened query 'CDM-Coding: This medication can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name.	Coder Import (b) (4) (b) (4)	10 Feb 2021 02:25:47
' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:07:15
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:26:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:26:38

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Aug 2020 19:25:29
User entered 'Pepcid'	Lalicia Roman (b) (4)	25 Aug 2020 19:24:49
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:07:41
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:32
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		04 Nov 2020 07:21:51
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	19 Oct 2020 19:33:05
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:46:57
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'acid reflux'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:37
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'unknown'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:39
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 19:28:08
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	25 Aug 2020 19:28:08
User opened query 'Data is required. Please complete.' (Site from System).	Lalicia Roman (b) (4)	25 Aug 2020 19:28:08
User entered empty.	(b) (4)	25 Aug 2020 19:24:49
	System	25 Aug 2020 19:24:49
	Lalicia Roman (b) (4)	25 Aug 2020 19:24:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:42
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4)	
	System	25 Aug 2020 19:28:52
User entered 'unknown' reason for change: Data Entry Error	Lalicia Roman (b) (4)	25 Aug 2020 19:28:52
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	25 Aug 2020 19:28:08
User entered empty.	Lalicia Roman (b) (4)	25 Aug 2020 19:24:49
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:45
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'as needed (PRN)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:49
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:51
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Oral (ORAL)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:53
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:56
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2018'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:09:58
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:10:00
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:11:26
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:24:49
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:11:31
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:24:49

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:24:49

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:24:49

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:24:49

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:12:04
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
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, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 19:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:27:40
Data point term sent to Coder	System	25 Aug 2020 19:26:35
User entered 'albuterol'	Lalicia Roman (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:12:07
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:12:34
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'asthma'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:02:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:12:19
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Actual dose unknown ' (Site from DM).	Emily Carney (b) (4) (b) (4)	02 Feb 2021 20:47:00
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 02:33:42
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 20:47:46
Signature has been broken.	Emily Carney (b) (4) (b) (4)	23 Nov 2020 20:47:46
User entered '2' reason for change: Data Entry Error	Emily Carney (b) (4)	23 Nov 2020 20:47:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:12:36
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'unknown'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:12:44
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'puff (PUFF)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		24 Nov 2020 18:57:52
User closed query 'Source states "2 puffs". please clarify' (Site from CRA).		24 Nov 2020 18:57:46
Query 'Source states "2 puffs". please clarify' answered with 'Updated' (Site from CRA).	Emily Carney (b) (4)	23 Nov 2020 20:47:53
User opened query 'Source states "2 puffs". please clarify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:14:33
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered empty.	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		24 Nov 2020 18:58:03
User closed query 'Source states every 4 hrs. please confirm' (Site from CRA).		24 Nov 2020 18:57:57
Query 'Source states every 4 hrs. please confirm' answered with 'Frequency is every 4 hours as needed' (Site from CRA).	Melissa Andrasko (b) (4)	23 Nov 2020 21:20:06
User opened query 'Source states every 4 hrs. please confirm' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:14:08
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'as needed (PRN)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:37
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:26:26
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:39
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:46
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:26:26
	(b) (4)	



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:48
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2000'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:50
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:56
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:14:58
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:26:26

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:26:26

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:26:26

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:26:26



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:41:28
Data point term sent to Coder Coding entries removed.	System Melissa Andrasko (b) (4)	19 Oct 2020 19:37:07 19 Oct 2020 19:36:55
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:30:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 19:30:31
Data point term sent to Coder User entered 'advil'	System Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:39 25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:10
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:29
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		11 Nov 2020 17:13:06
User signature succeeded.	Judith Martin (b) (4)	10 Nov 2020 10:24:42
User closed query 'Per DM CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Generalized, Back, Left Thigh, etc.). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 07:23:13
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	19 Oct 2020 19:37:10
Query 'Per DM CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Generalized, Back, Left Thigh, etc.). Reconcile and update as appropriate, otherwise clarify.' answered with 'done' (Site from DM).	Melissa Andrasko (b) (4)	19 Oct 2020 19:37:02
Signature has been broken.	Melissa Andrasko (b) (4)	19 Oct 2020 19:36:55
User entered 'HEADACHE AND generalized MUSCLE PAIN' reason for change: Data Entry Error	Melissa Andrasko (b) (4)	19 Oct 2020 19:36:55
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:47:38

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Generalized, Back, Left Thigh, etc.). Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:47:24
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'headache and muscle pain'	Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:50
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '200'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:52
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'mg (mg)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:15:58
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'as needed (PRN)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:16:00
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:16:03
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Oral (ORAL)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:16:06
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:31:39
User closed query 'Source states 1990. please confirm' ' (Site from CRA).		23 Nov 2020 17:31:36
Query 'Source states 1990. please confirm ' answered with 'Confirmed and updated' (Site from CRA).	Emily Carney (b) (4)	17 Nov 2020 21:11:38
Signature has been broken.	(b) (4) Emily Carney (b) (4)	17 Nov 2020 21:11:27
User entered 'UN UNK 1990' reason for change: Data Entry Error	(b) (4) Emily Carney (b) (4)	17 Nov 2020 21:11:27
User opened query 'Source states 1990. please confirm ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:16:33
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'UN UNK 2020'	(b) (4) Lalicia Roman (b) (4)	25 Aug 2020 19:27:13
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:18:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:18:59
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:19:00
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Lalicia Roman (b) (4)	25 Aug 2020 19:27:13
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		17 Nov 2020 18:19:02
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	25 Aug 2020 19:27:13



US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:27:13

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:27:13

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered empty.	System	25 Aug 2020 19:27:13

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
User closed query 'This entry is not present in AE log in source. please clarify. ' (Site from CRA).		18 Nov 2020 21:15:06
DataPoint Verified.		18 Nov 2020 21:15:03
Query 'This entry is not present in AE log in source. please clarify. ' answered with 'Reported in diary so not an AE. ' (Site from CRA).	Emily Carney (b) (4) (b) (4)	17 Nov 2020 21:12:08
User opened query 'This entry is not present in AE log in source. please clarify. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:20:17
User signature succeeded.	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:11:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:11:30
Data point term sent to Coder	System	01 Sep 2020 21:10:29
User entered 'Advil'	Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:08
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		05 Mar 2021 15:03:16
User closed query 'Per CDM: Please note, that 'Headache' is recorded on MH form with unknown start-date. Please verify this for possible duplicate or worsening, and update data if appropriate or confirm correct. Thank you.' (Site from DM).		01 Mar 2021 16:12:59
Query 'Per CDM: Please note, that 'Headache' is recorded on MH form with unknown start-date. Please verify this for possible duplicate or worsening, and update data if appropriate or confirm correct. Thank you.' answered with 'This headache was indicated because the participant had this as a reaction to their vaccine which was recorded in the diary.' (Site from DM).	Emily Carney (b) (4) (b) (4)	25 Feb 2021 21:19:37
User opened query 'Per CDM: Please note, that 'Headache' is recorded on MH form with unknown start-date. Please verify this for possible duplicate or worsening, and update data if appropriate or confirm correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:09:42
User closed query 'Per DM CLR: Response noted as "done" however, there is still no AE recorded. If the HEADACHE is considered a solicited local or systemic adverse reaction and meets the criteria outlined in the protocol or considered as an SAE, please add in the AE page. Otherwise provide confirmation in query response if HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:30:39
Query 'Per DM CLR: Response noted as "done" however, there is still no AE recorded. If the HEADACHE is considered a solicited local or systemic adverse reaction and meets the criteria outlined in the protocol or considered as an SAE, please add in the AE page. Otherwise provide confirmation in query response if HEADACHE did not meet the AE reporting criteria.' answered with 'The participant indication this event in the diary.' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	28 Oct 2020 15:49:29

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Response noted as "done" however, there is still no AE recorded. If the HEADACHE is considered a solicited local or systemic adverse reaction and meets the criteria outlined in the protocol or considered as an SAE, please add in the AE page. Otherwise provide confirmation in query response if HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 04:53:41
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4), (b) (6)	26 Oct 2020 04:53:41
' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Melissa Andrasko (b) (4)	19 Oct 2020 19:42:08
' answered with 'done' (Site from DM).		

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 Oct 2020 12:56:55
	Judith Martin (b) (4) (b) (4)	10 Sep 2020 20:53:03
User entered 'Headache'	Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:40
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '400'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:42
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'mg (mg)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:44
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Emily Dougherty (b) (4)	01 Sep 2020 21:10:21
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:46
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'as needed (PRN)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:48
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Emily Dougherty (b) (4)	01 Sep 2020 21:10:21
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:49
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Oral (ORAL)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:52
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered empty.	(b) (4)	
	Emily Dougherty (b) (4)	01 Sep 2020 21:10:21
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:54
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '27 Aug 2020'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:55
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:56
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'No (N)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:15:59
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered '27 Aug 2020'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
DataPoint Verified.		18 Nov 2020 21:16:01
User signature succeeded.	Judith Martin (b) (4)	10 Sep 2020 20:53:03
User entered 'Yes (Y)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	01 Sep 2020 21:10:21

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
User entered empty.	System	01 Sep 2020 21:10:21

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
User entered empty.	System	01 Sep 2020 21:10:21

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:26:17
User entered empty.	System	01 Sep 2020 21:10:21

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:29:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 19:29:50
Data point term sent to Coder	System	16 Nov 2020 19:29:22
User entered 'Flu vaccine'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:38
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:42
User entered 'Prevent influenza infection'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:44
User entered 'Unk'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:48
User entered 'mL (mL)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:50
User entered empty.	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:54
User entered 'once (ONCE)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:55
User entered empty.	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:00
User entered 'Intramuscular (INTRAMUSCULAR)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:02
User entered empty.	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:04
User entered '12 Oct 2020'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:06
User entered '0'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:09
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:10
User entered '12 Oct 2020'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:22:22
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	16 Nov 2020 19:28:59

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User entered empty.	System	16 Nov 2020 19:28:59

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User entered empty.	System	16 Nov 2020 19:28:59



US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:09:04
User entered empty.	System	16 Nov 2020 19:28:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 18:59:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 18:59:50
Data point term sent to Coder	System	18 Nov 2020 18:59:25
User entered 'Amoxicillin'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:42
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:45
User entered 'Tooth infection'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:49
User entered '500'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:50
User entered 'mg (mg)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:52
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:55
User entered 'three times daily (TID)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:56
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:59:58
User entered 'Oral (ORAL)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:00:00
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:00:02
User entered '29 Oct 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
DataPoint Verified.		03 Mar 2021 04:55:35
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '0'	(b) (4) Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:00:05
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:00:14
User entered '7 Nov 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
DataPoint Verified.		03 Mar 2021 04:55:38
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:35:34
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated as recommended' (Site from DM).	Emily Carney (b) (4) (b) (4)	28 Jan 2021 19:30:09
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	28 Jan 2021 19:29:59
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	28 Jan 2021 19:29:59
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:07:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:00:15
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 18:58:25



**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User entered '3'	System	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 17:46:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User entered '1'	System	18 Nov 2020 18:58:25

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:49:11
User entered '804 (804)'	System	18 Nov 2020 18:58:25

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:52:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 03:52:59
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:02:46
Data point term sent to Coder	System	18 Nov 2020 19:01:32
User entered 'Methylprednisolone'	Emily Carney (b) (4)	18 Nov 2020 19:01:12
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:02:48
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:02:53
User entered 'Tooth infection'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:02:56
User entered 'Unk'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:03:06
User entered 'Other (OTHER)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:03:34
User entered 'Pack'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:11
User entered 'unknown (UNKNOWN)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:13
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:29
User entered 'Oral (ORAL)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:32
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:35
User entered '29 Oct 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:41
User entered '0'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:46
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:04:56
User entered '2 Nov 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
DataPoint Verified.		03 Mar 2021 04:55:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'response updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:01:19
DataPoint Un-verified.	Lalicia Roman (b) (4)	29 Jan 2021 20:42:02
	(b) (4)	
	Lalicia Roman (b) (4)	29 Jan 2021 20:41:54
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4)	29 Jan 2021 20:41:54
	(b) (4)	
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:07:59
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:04:57
User entered 'Yes (Y)'	Emily Carney (b) (4)	18 Nov 2020 19:01:12
	(b) (4)	

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User entered empty.	System	18 Nov 2020 19:01:12

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User entered empty.	System	18 Nov 2020 19:01:12

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:42
User entered empty.	System	18 Nov 2020 19:01:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 14:25:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 14:25:02
Data point term sent to Coder	System	22 Jan 2021 14:24:06
Coding entries removed.	Lalicia Roman (b) (4)	22 Jan 2021 14:23:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:01:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:29:47
Data point term sent to Coder	System	18 Nov 2020 19:29:20
User entered 'Mucinex'	Emily Carney (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:19
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
DataPoint Verified.		03 Mar 2021 04:56:28
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).		25 Feb 2021 20:16:18
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Updated on AE form' (Site from DM).	Emily Carney (b) (4) (b) (4)	25 Feb 2021 13:18:17
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 20:56:42
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 16:31:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Participant had active Covid infection in November 2020 and took several medications to treat symptoms' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:23:55
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:23:12



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
User entered 'CONGESTION, SORE THROAT, AND COUGH as related to Covid 19 infection' reason for change: Data Entry Error	Lalicia Roman (b) (4)	22 Jan 2021 14:23:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 09:14:39
	(b) (4), (b) (6)	18 Nov 2020 21:01:32
User entered 'Congestion, sore throat, and cough'	Emily Carney (b) (4)	18 Nov 2020 19:29:03
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:34
User entered 'Unk'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:43
User entered 'mg (mg)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:44
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:46
User entered 'as needed (PRN)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:49
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:53
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:29:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:29:14
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:14
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:29:03
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:01:54
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
DataPoint Verified.		05 Mar 2021 15:04:10
User closed query 'Per CDM: It's noted this CM is indicated for treatment of 'Symptomatic Covid 19'. Kindly reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you. ' (Site from DM).		04 Mar 2021 14:53:39
User signature succeeded.	Judith Martin (b) (4) (b) (4)	03 Mar 2021 16:27:37
Query 'Per CDM: It's noted this CM is indicated for treatment of 'Symptomatic Covid 19'. Kindly reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you. ' answered with 'updated as requested' (Site from DM).	Emily Carney (b) (4) (b) (4)	03 Mar 2021 13:23:35
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	03 Mar 2021 13:21:41
Signature has been broken.	Emily Carney (b) (4) (b) (4)	03 Mar 2021 13:21:41
User entered '05 Nov 2020' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	03 Mar 2021 13:21:41
User opened query 'Per CDM: It's noted this CM is indicated for treatment of 'Symptomatic Covid 19'. Kindly reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:27:18
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:01:57
User entered 'UN Nov 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:02:03
User entered '0'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:02:05
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:04:17
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	03 Mar 2021 13:23:58
DataPoint Un-verified.	System	03 Mar 2021 13:23:58
Signature has been broken.	Emily Carney (b) (4)	03 Mar 2021 13:23:58
User entered '03 Dec 2020' reason for change: Data Entry Error	Emily Carney (b) (4)	03 Mar 2021 13:23:58
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	03 Mar 2021 13:21:41
User signature succeeded.	System	03 Mar 2021 13:21:41
DataPoint Verified.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
	(b) (4)	18 Nov 2020 21:02:09
User entered 'UN Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 21:02:09
	Emily Carney (b) (4)	18 Nov 2020 19:29:03
	(b) (4)	

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
DataPoint Verified.		03 Mar 2021 04:56:43
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:31:52
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'Participant had active Covid infection in November 2020' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:24:25
DataPoint Un-verified.	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:23:12
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:23:12

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 09:14:14
	(b) (4), (b) (6)	18 Nov 2020 21:02:14
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:29:03

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User entered empty.	System	18 Nov 2020 19:29:03

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User entered empty.	System	18 Nov 2020 19:29:03



**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:13:25
User entered empty.	System	18 Nov 2020 19:29:03

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:26:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:26:57
Data point term sent to Coder Coding entries removed.	System Emily Carney (b) (4)	03 Mar 2021 13:26:11 03 Mar 2021 13:25:36
User signature succeeded.	(b) (4) Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:37:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:37:47
Data point term sent to Coder User entered 'Tylenol'	System Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:30 18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:13
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
DataPoint Verified.		05 Mar 2021 15:07:24
User closed query 'Per CDM: Are you reporting headache related to 'Symptomatic Covid 19'? If yes, kindly update 'Indication' field on this CM form as appropriate. Then, please reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you.' (Site from DM).		04 Mar 2021 14:54:14
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
Query 'Per CDM: Are you reporting headache related to 'Symptomatic Covid 19'? If yes, kindly update 'Indication' field on this CM form as appropriate. Then, please reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you.' answered with 'updated as requested' (Site from DM).	(b) (4) Emily Carney (b) (4)	03 Mar 2021 13:25:46
DataPoint Un-verified.	(b) (4) Emily Carney (b) (4)	03 Mar 2021 13:25:36
Signature has been broken.	(b) (4) Emily Carney (b) (4)	03 Mar 2021 13:25:36
User entered 'headache due to covid-19' reason for change: Data Entry Error	(b) (4) Emily Carney (b) (4)	03 Mar 2021 13:25:36
User opened query 'Per CDM: Are you reporting headache related to 'Symptomatic Covid 19'? If yes, kindly update 'Indication' field on this CM form as appropriate. Then, please reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:35:41
Query 'Per CDM: Are you reporting headache related to 'Symptomatic Covid 19'. Kindly reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:32:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Are you reporting headache related to 'Symptomatic Covid 19'. Kindly reconcile start and end-dates recorded on this CM form with corresponding AE form if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:32:26
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:32:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Participant had active Covid 19 infection in November 2020' (Site from DM).	Lalicia Roman (b) (4) (b) (4)	22 Jan 2021 14:38:13
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:17:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:11:14
User entered 'Forehead pain'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:17
User entered 'Unk'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:19
User entered 'mg (mg)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:24
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:26
User entered 'once (ONCE)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:34
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:30
User entered 'Oral (ORAL)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:41
User entered empty.	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:43
User entered '8 Nov 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:44
User entered '0'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:46
User entered 'No (N)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:11:48
User entered '8 Nov 2020'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
DataPoint Verified.		03 Mar 2021 04:57:09
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.'	Lalicia Roman (b) (4)	22 Jan 2021 14:38:42
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.'	(b) (4)	
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.'	Lalicia Roman (b) (4)	22 Jan 2021 14:38:21
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lalicia Roman (b) (4)	22 Jan 2021 14:38:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 09:18:07
	(b) (4), (b) (6)	18 Nov 2020 21:11:50
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	18 Nov 2020 19:36:24

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User entered empty.	System	18 Nov 2020 19:36:24

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User entered empty.	System	18 Nov 2020 19:36:24

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:37
User entered empty.	System	18 Nov 2020 19:36:24

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:14
User closed query 'Aspirin not on Conmed log. please verify ' (Site from CRA).		27 Apr 2021 09:30:12
Query 'Aspirin not on Conmed log. please verify ' answered with 'updated con med log in source' (Site from CRA).	Emily Carney (b) (4) (b) (4)	08 Mar 2021 13:28:15
User opened query 'Aspirin not on Conmed log. please verify ' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 15:10:02
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 19:44:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 19:44:50
Data point term sent to Coder Coding entries removed.	System Emily Carney (b) (4) (b) (4)	04 Feb 2021 19:44:38 04 Feb 2021 19:44:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:22
PRODUCTION RELEASE (v12.003 EAB) (1725)		3037 of 3181

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 17:46:30**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Dec 2020 15:49:45
User entered 'Aspirin'	Jamie Fries (b) (4)	21 Dec 2020 15:48:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:49
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:51
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:14:07
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' answered with 'Updated as this is prophylaxis and thus is meant to prevent heart disease. There is not an underlying medical condition.' (Site from DM).	Emily Carney (b) (4) (b) (4)	04 Feb 2021 19:44:54
User entered 'Prevent heart disease' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	04 Feb 2021 19:44:25
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 02:35:46
User entered 'Blood thinner'	Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:54
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '81'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:56
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'mg (mg)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:57
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	21 Dec 2020 15:48:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:30:58
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'once daily (QD)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:00
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	21 Dec 2020 15:48:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:01
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Oral (ORAL)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:09
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:10
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '5 Nov 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:13
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '0'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:16
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		27 Apr 2021 09:31:20
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:13:14
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	04 Feb 2021 19:45:01
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	04 Feb 2021 19:44:25
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 02:36:07
User entered 'Yes (Y)'	Jamie Fries (b) (4) (b) (4)	21 Dec 2020 15:48:59

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EAB) (1725)

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**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	21 Dec 2020 15:48:59

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	21 Dec 2020 15:48:59

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '804 (804)'	System	21 Dec 2020 15:48:59



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:06
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Jan 2021 18:51:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 18:51:03
Data point term sent to Coder	System	13 Jan 2021 18:49:41
User entered 'Tylenol'	Emily Carney (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:12:42
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:53:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:52:18
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:51:34
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:58:14
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered 'Body aches, injection site pain, fever'	Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:31
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Unk'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:36
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'mg (mg)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:38
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:40
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'twice daily (BID)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:45
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Oral (ORAL)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:47
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:50
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '6 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:58:52
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered '0'	Emily Carney (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
DataPoint Verified.		03 Mar 2021 04:58:53
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'No (N)'	(b) (4) Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
User closed query 'Per CDM: Please verify if this CM is indicated for treatment of 'Symptomatic Covid 19'. If yes, kindly update 'Indication' field on this CM form as appropriate. Then, reconcile start and end-dates recorded on this CM form with corresponding AE form. Thank you.' (Site from DM).		04 Mar 2021 15:03:27
Query 'Per CDM: Please verify if this CM is indicated for treatment of 'Symptomatic Covid 19'. If yes, kindly update 'Indication' field on this CM form as appropriate. Then, reconcile start and end-dates recorded on this CM form with corresponding AE form. Thank you.' answered with 'This was not related to Covid-19 symptoms, this was related to the participant's first dose. Please provide guidance if you would like this removed since there is no AE that matches it because we were not supposed to record any reactions to the vaccine.' (Site from DM).	Emily Carney (b) (4) (b) (4)	03 Mar 2021 13:40:09
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:58:59
User opened query 'Per CDM: Please verify if this CM is indicated for treatment of 'Symptomatic Covid 19'. If yes, kindly update 'Indication' field on this CM form as appropriate. Then, reconcile start and end-dates recorded on this CM form with corresponding AE form. Thank you.' (Site from DM).		25 Feb 2021 20:21:51
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:25:24
User entered '9 Jan 2021'	Emily Carney (b) (4) (b) (4)	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:50:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES, INJECTION SITE PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, INJECTION SITE PAIN, FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:20:43
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:10:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES, INJECTION SITE PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, INJECTION SITE PAIN, FEVER did not meet the AE reporting criteria. ' answered with 'updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	05 Mar 2021 13:23:45
DataPoint Un-verified.	Emily Carney (b) (4) (b) (4)	05 Mar 2021 13:23:37
Signature has been broken.	Emily Carney (b) (4) (b) (4)	05 Mar 2021 13:23:37

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4)	05 Mar 2021 13:23:37
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the BODY ACHES, INJECTION SITE PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of BODY ACHES, INJECTION SITE PAIN, FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 22:16:09
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 04:59:01
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
User entered 'Yes (Y)'	Emily Carney (b) (4)	13 Jan 2021 18:48:51



**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
User entered '2'	System	13 Jan 2021 18:48:51

**US3802034**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
User entered '1'	System	13 Jan 2021 18:48:51

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:07:43
User entered '804 (804)'	System	13 Jan 2021 18:48:51

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:11:50
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
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: MOMETASONE FUROATE, PRODUCTSYNONYM: ASMANEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Feb 2021 21:22:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:22:00
Data point term sent to Coder	System	25 Feb 2021 21:21:40
User entered 'asmanex'	Jamie Fries (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:11:52
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'No (N)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:11:55
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'asthma'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:11:57
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'unknown'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:11:58
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'puff (PUFF)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:00
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:09
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'twice daily (BID)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:10
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:12
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:14
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:16
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:20
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'I'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:24
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41



US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:26
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Feb 2021 21:20:41

US3802034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 17:46:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
DataPoint Verified.		05 Mar 2021 15:12:28
User signature succeeded.	Judith Martin (b) (4)	03 Mar 2021 16:27:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	25 Feb 2021 21:20:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 21:20:46
User entered 'No (N)' reason for change: Data Entry Error	Jamie Fries (b) (4)	25 Feb 2021 21:20:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:20:41
User entered empty.	Jamie Fries (b) (4)	25 Feb 2021 21:20:41
	(b) (4)	

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 12 Aug 2021 17:46:30**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '2'	System	25 Feb 2021 21:20:41

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '1'	System	25 Feb 2021 21:20:41

US3802034

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 12 Aug 2021 17:46:30**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:46:28
User entered '804 (804)'	System	25 Feb 2021 21:20:41

US3802034

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 17:46:30**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:25:24
	(b) (4)	
User entered 'No (N)'	Emily Carney (b) (4)	08 Feb 2021 13:28:40
	(b) (4)	

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'USA-US098-2020-MRNA-1273-P301000003'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Judith'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Martin'	System	10 Nov 2020 17:13:29



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '3420 Fifth Ave'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Pittsburgh'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered 'NJ'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'PA'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '15213'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'US'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '3'	System	11 Jan 2021 17:47:51
User entered '2'	System	30 Nov 2020 20:29:09
User entered '1'	System	10 Nov 2020 17:14:17

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'USA-US098-2020-MRNA-1273-P301000003'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Judith'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Martin'	System	10 Nov 2020 17:13:29



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '3420 Fifth Ave'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Pittsburgh'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered 'NJ'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'PA'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '15213'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'US'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '3'	System	11 Jan 2021 17:47:51
User entered '2'	System	30 Nov 2020 20:29:09
User entered '1'	System	10 Nov 2020 17:14:17

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
User entered '10/Nov/2020 17:14'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 17:46:30

**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.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'I'		10 Nov 2020 17:14:17



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'USA-US098-2020-MRNA-1273-P301000003'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Judith'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered 'Martin'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered '3420 Fifth Ave'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered 'Pittsburgh'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered 'NJ'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'PA'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered '15213'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'US'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '3'	System	11 Jan 2021 17:47:51
User entered '2'	System	30 Nov 2020 20:29:09
User entered '1'	System	10 Nov 2020 17:14:17



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '30/Nov/2020 20:29'	(b) (4) System	30 Nov 2020 20:29:09

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 17:46:30

**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)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:47:39
User entered 'I'		30 Nov 2020 20:29:09

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'USA-US098-2020-MRNA-1273-P301000003'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered 'Judith'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Martin'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '3420 Fifth Ave'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Pittsburgh'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered 'NJ'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'PA'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '15213'	System	10 Nov 2020 17:13:29



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'US'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '3'	System	11 Jan 2021 17:47:51
User entered '2'	System	30 Nov 2020 20:29:09
User entered '1'	System	10 Nov 2020 17:14:17

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
User entered '11/Jan/2021 12:47'	(b) (4) System	11 Jan 2021 17:47:51

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 17:46:30

**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)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:47:55
User entered 'I'		11 Jan 2021 17:47:51

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'USA-US098-2020-MRNA-1273-P301000003'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29



**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 17:46:30**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'No (N)'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Judith'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered (b) (6)	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Martin'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User entered '3420 Fifth Ave'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'Pittsburgh'	System	10 Nov 2020 17:13:29



US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered 'NJ'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered 'PA'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	23 Mar 2021 17:57:42
Signature has been broken.	System	23 Mar 2021 17:57:42
User entered empty.	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 14:33:51
Reviewed for Safety.		10 Nov 2020 17:14:05
User entered '15213'	System	10 Nov 2020 17:13:29

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 20:28:58
DataPoint Verified.		18 Nov 2020 14:33:51
User entered 'US'	System	10 Nov 2020 17:14:17

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 17:46:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 17:57:42
User signature succeeded.	Judith Martin (b) (4)	28 Jan 2021 15:27:03
	(b) (4)	
User entered '3'	System	11 Jan 2021 17:47:51
User entered '2'	System	30 Nov 2020 20:29:09
User entered '1'	System	10 Nov 2020 17:14:17

**US3802034**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 12 Aug 2021 17:46:30**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
User entered '23/Mar/2021 13:57'	(b) (4) System	23 Mar 2021 17:57:42

US3802034

Folder: SAE USA-US098-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 17:46:30

**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)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:59:36
User signature succeeded.	Judith Martin (b) (4)	25 Mar 2021 17:58:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:57:42