

US3802185 (Prod: UPMC University Center)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:31:00

All time stamps listed in this document are displayed in GMT

US3802185

Form: Participant Creation

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

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[Participant ID](#)

US3802185

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	52
Age Units	YEARS
Age (Derived)	52
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	True
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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Date of Informed Consent ( <i>dd MMM yyyy</i> )	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

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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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

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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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	SEASONAL ALLERGIES
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 (2)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	HIGH CHOLESTEROL
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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	TONSILS REMOVED
Start date (dd MMM yyyy)	UN UNK 1983
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	GERD
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 (5)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	LEFT WRIST 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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	ALLERGY RELATED ASTHMA
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Condition	BASAL CELL REMOVAL
Start date (dd MMM yyyy)	UN UNK 2010
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)	
Stop date completely unknown	True
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: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:40 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:40
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	221 lb
BMI ( <i>xxx.x</i> )	35.74492 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 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) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*) 9 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	9 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 01 Feb 2021 16:29:45

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112652

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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:40
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	INFRARED
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 12:56
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 12:18

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) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

12:05 (24 HR)

Collection date and time (derived)

9 SEP 2020 12:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:53	9 SEP 2020 11:53
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:45

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:57

PC Open Date & Time

09 SEP 2020 12:38

PC Close Date & Time

09 SEP 2020 15:08



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**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 98.0 °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	09 SEP 2020 20:48
PC Open Date & Time	09 SEP 2020 16:03
PC Close Date & Time	10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

10 SEP 2020 19:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 17:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

14 SEP 2020 19:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 09:18

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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

09 SEP 2020 12:59

PC Open Date & Time

09 SEP 2020 12:38

PC Close Date & Time

09 SEP 2020 15:08



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**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

09 SEP 2020 20:49

PC Open Date & Time

09 SEP 2020 16:03

PC Close Date & Time

10 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**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

10 SEP 2020 19:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**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

11 SEP 2020 15:02

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b> Please select one response below	None <input type="radio"/> 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 type="radio"/>
Please record - <b>REDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site redness with the ruler provided.	
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/> No <input type="radio"/>
Please record - <b>SWELLING/HARDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b> Please select one response below	None <input type="radio"/> 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	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**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

13 SEP 2020 17:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**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

14 SEP 2020 19:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	16 SEP 2020 09:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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 ☐



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 12:58
PC Open Date & Time	09 SEP 2020 12:38
PC Close Date & Time	09 SEP 2020 15:08

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**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 ☐

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 20:49
PC Open Date & Time	09 SEP 2020 16:03
PC Close Date & Time	10 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 ☒

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:13
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:02
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 ☐

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EAB) (1725)

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US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:42
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:48
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 09:18
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3802185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

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*



US3802185

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	VISIT2

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

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)	12 OCT 2020
Time of assessment (00:00-23:59)	15:11 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 15:11
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)	102 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

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)	12 OCT 2020
Time of assessment (00:00-23:59)	16:29 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 16:29
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	96 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)	87 mmHg
Diastolic Blood Pressure units	MMHG



US3802185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

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.*

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 12 OCT 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 15:58 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 15:58

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

US3802185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

15:51 (24 HR)

Collection date and time (derived)

12 OCT 2020 15:51

US3802185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:52	12 OCT 2020 15:52
Nasopharyngeal Swab 2	No		

US3802185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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

97.7 °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

12 OCT 2020 16:30

PC Open Date & Time

12 OCT 2020 16:18

PC Close Date & Time

12 OCT 2020 18:48

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	13 OCT 2020 08:32
PC Open Date & Time	12 OCT 2020 19:43
PC Close Date & Time	13 OCT 2020 11:59



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

13 OCT 2020 15:23

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

15 OCT 2020 10:38

---

PC Open Date & Time

14 OCT 2020 12:00

---

PC Close Date & Time

15 OCT 2020 11:59

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US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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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

99.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

16 OCT 2020 17:13

---

PC Open Date & Time

16 OCT 2020 12:00

---

PC Close Date & Time

17 OCT 2020 11:59

---

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

17 OCT 2020 21:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:26

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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

12 OCT 2020 16:30

PC Open Date & Time

12 OCT 2020 16:18

PC Close Date & Time

12 OCT 2020 18:48

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**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

13 OCT 2020 08:32

PC Open Date & Time

12 OCT 2020 19:43

PC Close Date & Time

13 OCT 2020 11:59



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**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

13 OCT 2020 15:23

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**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

15 OCT 2020 10:39

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b> Please select one response below	None <input type="radio"/> 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 type="radio"/>
Please record - <b>REDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site redness with the ruler provided.	
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/> No <input type="radio"/>
Please record - <b>SWELLING/HARDNESS AT INJECTION SITE (in mm)</b>  Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b> Please select one response below	None <input type="radio"/> 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	
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**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

16 OCT 2020 17:13

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**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

17 OCT 2020 21:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**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

18 OCT 2020 19:26

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**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 ☐

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 16:31
PC Open Date & Time	12 OCT 2020 16:18
PC Close Date & Time	12 OCT 2020 18:48



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**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 ☐

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 08:32
PC Open Date & Time	12 OCT 2020 19:43
PC Close Date & Time	13 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 ☒

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 15:24
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 ☒

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 10:39
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**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 ☐

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Yes ☐

PC Time stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 ☒

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 17:13
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 ☒

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 21:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**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 ☒

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:26
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3802185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3802185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT3

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 14:53
Temperature (xxx.x)	36 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3802185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 NOV 2020
Collection time (00:00-23:59)	14:58 (24 HR)
Collection date and time (derived)	11 NOV 2020 14:58



US3802185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:59

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 75
Have 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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2020 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 82
Have 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"/>



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2020 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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15 DEC 2020 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2020 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 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"/>



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59
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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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°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 ☐



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 <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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

05 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 159

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 21:44:16

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 MAR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 16:38:25

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 16:11:20
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 13:07:48
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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

06 APR 2021 18:21:52

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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

12 APR 2021 13:12:21

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 11:18:51

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 15:51:43
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

<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	30 APR 2021 00:16:41
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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 <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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAY 2021 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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°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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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14 SEP 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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°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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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26 OCT 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59
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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐  
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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐ 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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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°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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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12 JUL 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**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°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 ☐

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59



US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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="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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59
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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

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US3802185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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"/>

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

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[Patient Cloud Close Date & Time](#)

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15 NOV 2022 23:59

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**US3802185**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 12 Aug 2021 13:31:00**

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		02 MAR 2021 21:43:49

US3802185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802185

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

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

Visit date (dd MMM yyyy)	11 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:49:49

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:41
Temperature (xxx.x)	99.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

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.*



US3802185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

08:45 (24 HR)

Collection date and time (derived)

11 MAR 2021 08:45

US3802185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3802185**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

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*

**US3802185**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Date of Contact	11 NOV 2020
Time of Contact	14:53
Date and Time of Contact (derived)	11 NOV 2020 14:53
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	97 %	
O2 Saturation Units	%	
Temperature	36 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	95 %	
O2 Saturation Units	%	
Temperature	99.5 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 (3)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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 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 (3)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	89 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	92 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	95 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	95 %
---------------	------

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

Temperature	100.5 F
-------------	---------

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

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

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

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %
---------------	------

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

Temperature	99 F
-------------	------

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

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

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

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	95 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	95 %
---------------	------

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

Temperature	99 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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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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Form: Symptom Log (11)

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Generated On: 12 Aug 2021 13:31:00

	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	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 (12)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %
---------------	------

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

Temperature	98.8 F
-------------	--------

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

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

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

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Form: Symptom Log (12)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %
---------------	------

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

Temperature	98.9 F
-------------	--------

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

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

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

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 (15)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (17)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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 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 (17)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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"/>



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 ☐

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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"/>

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 ☐

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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"/>

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	97 %
---------------	------

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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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

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EAB) (1725)

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US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 ☐

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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"/>

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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	96 %
---------------	------

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

Temperature	98.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

	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"/>

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

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 ☐

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

Date of Visit	11 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	11 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

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

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 14 NOV 2020

End Date 15 NOV 2020

Oxygen Saturation 89 %

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 \_\_\_\_\_

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

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

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Feb 2021 16:29:43

Generated On: 12 Aug 2021 13:31:00

---

[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

US3802185

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 NOV 2020
Day 5	Yes	15 NOV 2020
Day 7	Yes	17 NOV 2020
Day 9	Yes	19 NOV 2020
Day 14	Yes	24 NOV 2020
Day 21	Yes	01 DEC 2020
Day 28	Yes	08 DEC 2020

US3802185

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 14:53
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802185

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3802185

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 31 Mar 2021 19:49:49

Generated On: 12 Aug 2021 13:31:00

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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



US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 DEC 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	08 DEC 2020 08:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

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.*

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 DEC 2020

US3802185

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

Form: Visit Date

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

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

Visit date (dd MMM yyyy)	8 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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US3802185

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 18:41:43

Generated On: 12 Aug 2021 13:31:00

Date of updated informed consent ( <i>dd MMM yyyy</i> )	8 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> )	8 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

US3802185

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Height	163.5 cm
Weight	180 lb
BMI (xxx.x)	30.60655

US3802185

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Height	163.5 cm
Weight	180 lb
BMI (xxx.x)	30.60655
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)	8 JAN 2021
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 08:41
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	INFRARED
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3802185

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Height	163.5 cm
Weight	180 lb
BMI (xxx.x)	30.60655
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)	8 JAN 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 09:46
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG



US3802185

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

Form: Physical Examination

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

8 JAN 2021

---

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

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US3802185

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

Form: Pregnancy Test

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	8 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3802185

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

Form: Exposure

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

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) 8 JAN 2021

What was the treatment time? (00:00-23:59) 09:18 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 09:18

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

US3802185

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

8 JAN 2021 09:10

US3802185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	09:13
Collection Date and Time (derived)	8 JAN 2021 09:13

US3802185

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

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3802185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3802185

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 08:45
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

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)	5 FEB 2021
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 09:46
Temperature (xxx.x)	96.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3802185

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

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.*

US3802185

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	5 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3802185

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 FEB 2021

What was the treatment time? (00:00-23:59) 09:14 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 09:14

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

US3802185

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3802185

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:35:25

Generated On: 12 Aug 2021 13:31:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3802185

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3802185

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:41 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 08:41
Temperature ( <i>xxx.x</i> )	99.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3802185

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

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.*

US3802185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 14:53:11

Generated On: 12 Aug 2021 13:31:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

08:45 (24 HR)

Collection date and time (derived)

11 MAR 2021 08:45

US3802185

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 14:47:20

Generated On: 12 Aug 2021 13:31:00

AEID	USA-US098-2020-MRNA-1273-P30 1000004
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)	11 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)	2 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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US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 14:47:20

Generated On: 12 Aug 2021 13:31:00

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT USING ALBUTEROL INHALER AND TAKING TYLENOL FOR HEADACHES. STARTED ASPIRIN TO PREVENT DVTS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) **19 Feb 2021 14:47:20**

**Generated On: 12 Aug 2021 13:31:00**

---

Admitted to ICU Derived (CSA Programming Field Only)

---

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 14:47:20

Generated On: 12 Aug 2021 13:31:00

AEID

Adverse event

BLOODY SPUTUM

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)

20 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 NOV 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

PRODUCTION RELEASE (v12.003

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US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 14:47:20

Generated On: 12 Aug 2021 13:31:00

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

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

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

Yes ☒

No ☐

---

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

---

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐  
No ☒

Indication ALLERGY RELATED ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:47:21

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:47:21

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (3)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION

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 (3)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication CLARITIN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	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 1975	
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 (5)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication NORETHINDRONE

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration .35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication OMEGA 3 KRILL OIL

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 14:47:21

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Name of Medication CALCIUM W/ D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 630/500

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

If dose unit is Other, specify MG/IU

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	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 (8)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	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 (9)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication KEFLEX

Prophylaxis Yes ☐  
No ☒

Indication POST OPP SURGERY

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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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	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)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 10 OCT 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication DVT PREVENTION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

	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)	17 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"/>

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 14:47:21

Generated On: 12 Aug 2021 13:31:00

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



US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Feb 2021 16:29:42

Generated On: 12 Aug 2021 13:31:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 OCT 2020	LIPOSUCTION	Other	ELECTIVE

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:31:00

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:31:00

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

SAEID	USA-US098-2020-MRNA-1273-P301000004
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

SAEID	USA-US098-2020-MRNA-1273-P301000004
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 12:29
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

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

SAEID	USA-US098-2020-MRNA-1273-P301000004
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/DEC/2020 21:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 01 Feb 2021 16:29:44

Generated On: 12 Aug 2021 13:31:00

SAEID	USA-US098-2020-MRNA-1273-P301000004
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	JUDITH
Investigator's Last Name	MARTIN
Site Address: Street	3420 FIFTH AVE
Site Address: City	PITTSBURGH
Site Address: State	PA
Site Address: Postal Code	15213
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/DEC/2020 16:21
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

US3802185 (Prod: UPMC University Center)

**US3802185**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:31:00**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'US3802185'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:34:34

US3802185

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:33
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:43:57

US3802185

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:33
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:34:36

**US3802185**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:39:33
User entered 'Clinic (Clinic)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:43:57

**US3802185**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'SCRN'	System	09 Sep 2020 15:43:57

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:34:37

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '52'	(b) (4) Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36



**US3802185**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:00**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'YEARS'	System	09 Sep 2020 16:33:36

**US3802185**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:31:00**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '52'	System	09 Sep 2020 15:46:10

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered 'Female (F)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36



US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:31:00

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:00
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:36

US3802185

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:00

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered '9 Sep 2020'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

**US3802185**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:00**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Sep 2020'	System	09 Sep 2020 15:46:10

**US3802185**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:00**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2020'	System	09 Sep 2020 15:46:10



US3802185

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:00

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered 'Amendment 3 (3)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

US3802185

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:00

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

**US3802185**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:00**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered empty.	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

US3802185

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered empty.	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

**US3802185**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:00**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:10

US3802185

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:31:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:05
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:34:36

**US3802185**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:31:00**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'I'	System	09 Sep 2020 15:46:14

US3802185

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:31:00

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:40:24
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:46:14



US3802185

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:31:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:07:23
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:33:52

US3802185

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 16:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 16:35:49
Data point term sent to Coder	System	09 Sep 2020 16:34:40
User entered 'Seasonal Allergies'	Dominic Kramer (b) (4)	09 Sep 2020 16:34:10

US3802185

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:31:00

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:10



**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:10

**US3802185**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:10

US3802185

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Investigations, HLT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 16:35:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 16:35:48
Data point term sent to Coder	System	09 Sep 2020 16:34:40
User entered 'High Cholesterol'	Dominic Kramer (b) (4)	09 Sep 2020 16:34:32

US3802185

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:00

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:32

US3802185

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4)	09 Sep 2020 16:34:32

US3802185

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:31:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:32

**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:32



**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:32

**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 2010'	System	09 Sep 2020 16:34:32

**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2010'	System	09 Sep 2020 16:34:32

**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:32

**US3802185**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:32

US3802185

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:23:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:23:51
Data point term sent to Coder	System	09 Sep 2020 16:35:42
User entered 'Tonsils Removed'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57

US3802185

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:00

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 1983'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57

**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57



**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57

**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57

**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:34:57

US3802185

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 1983'	System	09 Sep 2020 16:34:57

**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '1983'	System	09 Sep 2020 16:34:57

US3802185

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:31:00

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:57

**US3802185**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:34:57

US3802185

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:36:42
Data point term sent to Coder	System	09 Sep 2020 16:35:42
User entered 'GERD'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19



US3802185

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:00

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19

**US3802185**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19

US3802185

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19

**US3802185**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19

US3802185

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:19

**US3802185**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 2010'	System	09 Sep 2020 16:35:19

**US3802185**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2010'	System	09 Sep 2020 16:35:19

**US3802185**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:35:19



US3802185

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:31:00

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:35:19

US3802185

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:31:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Wrist fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:36:42
Data point term sent to Coder	System	09 Sep 2020 16:35:45
User entered 'Left Wrist Fracture'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 2005'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 2005'	System	09 Sep 2020 16:35:42



**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2005'	System	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:35:42

**US3802185**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:35:42

US3802185

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:09:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Allergic asthma - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:28:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:28:50
Data point term sent to Coder	System	09 Sep 2020 16:36:46
User entered 'Allergy Related Asthma'	Dominic Kramer (b) (4)	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 2020'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4)	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:04



**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:04

US3802185

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:31:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 2020'	System	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2020'	System	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:36:04

**US3802185**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:36:04

US3802185

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User closed query 'Per DM CLR: Please specify the location of BASAL CELL REMOVAL. 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).		30 Oct 2020 12:27:44
Query 'Per DM CLR: Please specify the location of BASAL CELL REMOVAL. 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. This is exactly what they reported. ' (Site from DM).	Emily Carney (b) (4) (b) (4)	23 Oct 2020 14:22:16
User opened query 'Per DM CLR: Please specify the location of BASAL CELL REMOVAL. 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)	21 Oct 2020 13:13:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:37:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:37:48
Data point term sent to Coder	System	09 Sep 2020 16:36:48
User entered 'Basal Cell Removal'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35

US3802185

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:00

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35



US3802185

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:31:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:09:13
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'Jan 2010'	System	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '2010'	System	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:36:35

**US3802185**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:36:35

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:38:01



US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '11:40'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

**US3802185**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '9 Sep 2020 11:40'	System	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '66' in	(b) (4)	
	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01
	(b) (4)	
DataPoint set to visible.	System	09 Sep 2020 15:46:14

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '221' lb	(b) (4)	
	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01
	(b) (4)	
DataPoint set to visible.	System	09 Sep 2020 15:46:14

**US3802185**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered '35.74492'	System	09 Sep 2020 16:38:01
DataPoint set to visible.	System	09 Sep 2020 15:46:14

**US3802185**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'kg/m2'	System	09 Sep 2020 16:38:01
DataPoint set to visible.	System	09 Sep 2020 15:46:14

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:30:37
Query 'Per CDM: Subject was screened and dosed on Jennifer Nagg the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' answered with 'updated to nd' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:57:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:57:29
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Vital Signs form at Screening and Visit 1 Day 1. Please record "ND" for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP as per CCGs version 2.0 page 25. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:53:42
User entered '97.4' F	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:38:01



US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4)	24 Nov 2020 13:57:29
User entered 'Other (Other)'	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4)	24 Nov 2020 13:57:29
User entered 'Infrared'	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 13:57:29
User entered '90'	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

**US3802185**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'bpm'	System	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 13:57:29
User entered '18'	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'breaths/min'	System	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 13:57:29
User entered '105'	Dominic Kramer (b) (4)	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'mmHg'	System	09 Sep 2020 16:38:01



US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Nov 2020 13:57:29
User entered '74'	Jennifer Nagg (b) (4)	09 Sep 2020 16:38:01
	(b) (4)	

**US3802185**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered 'mmHg'	System	09 Sep 2020 16:38:01

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06

US3802185

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06

US3802185

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:38:32

**US3802185**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:38:32

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06



US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

**US3802185**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:31:00**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:31:00

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:06

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21



US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Urine (URINE)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Negative (NEGATIVE)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:21

**US3802185**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User entered empty.	System	09 Sep 2020 16:39:21

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:39:45



US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45



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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

**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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

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 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'I'	Dominic Kramer (b) (4)	09 Sep 2020 16:39:45



US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

US3802185

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:31:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:24:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:45

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:13

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:13

US3802185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:44:13

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'VISIT1'	System	09 Sep 2020 15:44:13

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:45:21



US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '112652'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:45:21

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 15:45:21

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

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)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	09 Sep 2020 15:44:26

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

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)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:26

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:26

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:31:00**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:26

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	09 Sep 2020 15:44:26

US3802185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:31:00

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:29:40
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'entered as no' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:50:52
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:50:44
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 21:37:01
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:48:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:48:15



US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:01:52
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:14
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:50:42
User entered '66' in	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Oct 2020 16:46:14
User entered '221' lb	Jennifer Nagg (b) (4)	09 Sep 2020 17:26:53
	(b) (4)	

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:01:52
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:14
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:50:42
User entered '66' in	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Oct 2020 16:46:14
User entered '221' lb	Jennifer Nagg (b) (4)	09 Sep 2020 17:26:53
	(b) (4)	

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '11:40'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53



US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '9 Sep 2020 11:40'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '97.4' F	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Other (Other)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Infrared'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '90'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'bpm'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '18'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'breaths/min'	System	09 Sep 2020 17:26:53



US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '105'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '74'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:01:52
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	16 Oct 2020 16:46:14
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:50:42
User entered '66' in	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	16 Oct 2020 16:46:14
User entered '221' lb	Jennifer Nagg (b) (4)	09 Sep 2020 17:26:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12:56'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '9 Sep 2020 12:56'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '97.9' F	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Other (Other)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Infrared'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '88'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'bpm'	System	09 Sep 2020 17:26:53



US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '18'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'breaths/min'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '111'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered '78'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	09 Sep 2020 17:26:53

US3802185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:58

US3802185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:39:58



US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 12:25:57
Query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' answered with 'done' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	20 Oct 2020 20:15:01
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Nagg (b) (4) (b) (4)	20 Oct 2020 20:14:56
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:18:19
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:40:18

US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	20 Oct 2020 20:14:56
	(b) (4)	
User entered '9 Sep 2020'	Dominic Kramer (b) (4)	09 Sep 2020 16:40:18
	(b) (4)	

US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	20 Oct 2020 20:14:56
	(b) (4)	
User entered 'Urine (URINE)'	Dominic Kramer (b) (4)	09 Sep 2020 16:40:18
	(b) (4)	

US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	20 Oct 2020 20:14:56
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Dominic Kramer (b) (4)	09 Sep 2020 16:40:18
	(b) (4)	

US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:01:58
Query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' answered with 'updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	29 Oct 2020 14:55:44
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	29 Oct 2020 14:55:40
User opened query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:26:03
User entered empty; reason for change Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	20 Oct 2020 20:14:56
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:40:18

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:18

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:18

US3802185

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered empty.	System	09 Sep 2020 16:40:18



US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

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)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12:18'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:44

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '9 Sep 2020 12:18'	System	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Left Arm (LEFT ARM)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:56:44



US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'ONCE'	System	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 16:56:44

US3802185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:37

US3802185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:37

US3802185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12:05'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:37

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '9 Sep 2020 12:05'	System	09 Sep 2020 16:40:37

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '9 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:40:56



US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '11:53'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:56

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '9 Sep 2020 11:53'	System	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:40:56

**US3802185**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered empty.	System	09 Sep 2020 16:40:56

US3802185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	09 Sep 2020 16:56:58



**US3802185**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	09 Sep 2020 16:56:58

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:57:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3235e880-6b60-42c2-a4f7-5a2b8f1a7a58'	System	09 Sep 2020 16:58:01
User entered 'Yes (Y)'	System	09 Sep 2020 16:58:01

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:57:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3235e880-6b60-42c2-a4f7-5a2b8f1a7a58'	System	09 Sep 2020 16:58:01
User entered '97.9'	System	09 Sep 2020 16:58:01

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:57:51', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3235e880-6b60-42c2-a4f7-5a2b8f1a7a58'	System	09 Sep 2020 16:58:01
User entered 'No (N)'	System	09 Sep 2020 16:58:01

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:57:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3235e880-6b60-42c2-a4f7-5a2b8f1a7a58'	System	09 Sep 2020 16:58:01
User entered '09 Sep 2020 12:57'	System	09 Sep 2020 16:58:01

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 12:38'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 15:08'	System	09 Sep 2020 16:56:44



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:48:25', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '778d0e61-57db-4fbb-b816-0888dda45515'	System	10 Sep 2020 00:48:44
User entered 'Yes (Y)'	System	10 Sep 2020 00:48:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:48:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '778d0e61-57db-4fbb-b816-0888dda45515'	System	10 Sep 2020 00:48:44
User entered '98.0'	System	10 Sep 2020 00:48:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:48:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '778d0e61-57db-4fbb-b816-0888dda45515'	System	10 Sep 2020 00:48:44
User entered 'No (N)'	System	10 Sep 2020 00:48:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:48:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '778d0e61-57db-4fbb-b816-0888dda45515'	System	10 Sep 2020 00:48:44
User entered '09 Sep 2020 20:48'	System	10 Sep 2020 00:48:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 2'	System	09 Sep 2020 16:56:44



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:12:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'acec1935-2897-4662-9683-fad448c8c987'	System	10 Sep 2020 23:13:11
User entered 'Yes (Y)'	System	10 Sep 2020 23:13:11

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:12:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'acec1935-2897-4662-9683-fad448c8c987'	System	10 Sep 2020 23:13:11
User entered '98.2'	System	10 Sep 2020 23:13:11

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:03', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'acec1935-2897-4662-9683-fad448c8c987'	System	10 Sep 2020 23:13:11
User entered 'No (N)'	System	10 Sep 2020 23:13:11

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:08', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'acec1935-2897-4662-9683-fad448c8c987'	System	10 Sep 2020 23:13:11
User entered '10 Sep 2020 19:13'	System	10 Sep 2020 23:13:11

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 3'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:26', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b80b7fba-dcad-4153-bf00-2ef3e77a8e6d'	System	11 Sep 2020 19:01:43
User entered 'Yes (Y)'	System	11 Sep 2020 19:01:43



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b80b7fba-dcad-4153-bf00-2ef3e77a8e6d' User entered '98.2'	System	11 Sep 2020 19:01:43
	System	11 Sep 2020 19:01:43

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:35', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b80b7fba-dcad-4153-bf00-2ef3e77a8e6d'	System	11 Sep 2020 19:01:43
User entered 'No (N)'	System	11 Sep 2020 19:01:43

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:42', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b80b7fba-dcad-4153-bf00-2ef3e77a8e6d'	System	11 Sep 2020 19:01:43
User entered '11 Sep 2020 15:01'	System	11 Sep 2020 19:01:43

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 4'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 5'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:11', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c7f43d42-9cf8-4e5b-b7eb-ea06ffb02b6a'	System	13 Sep 2020 21:41:24
User entered 'Yes (Y)'	System	13 Sep 2020 21:41:24



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:16', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c7f43d42-9cf8-4e5b-b7eb-ea06ffb02b6a'	System	13 Sep 2020 21:41:24
User entered '98.3'	System	13 Sep 2020 21:41:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:19', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c7f43d42-9cf8-4e5b-b7eb-ea06ffb02b6a'	System	13 Sep 2020 21:41:24
User entered 'No (N)'	System	13 Sep 2020 21:41:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:23', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c7f43d42-9cf8-4e5b-b7eb-ea06ffb02b6a'	System	13 Sep 2020 21:41:24
User entered '13 Sep 2020 17:41'	System	13 Sep 2020 21:41:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 6'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:47:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'e4a34dfc-5cea-44a1-9a16-ebb8d23300c7'	System	14 Sep 2020 23:48:08
User entered 'Yes (Y)'	System	14 Sep 2020 23:48:08

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:47:56', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'e4a34dfc-5cea-44a1-9a16-ebb8d23300c7'	System	14 Sep 2020 23:48:08
User entered '98.6'	System	14 Sep 2020 23:48:08



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'e4a34dfc-5cea-44a1-9a16-ebb8d23300c7'	System	14 Sep 2020 23:48:08
User entered 'No (N)'	System	14 Sep 2020 23:48:08

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:06', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'e4a34dfc-5cea-44a1-9a16-ebb8d23300c7'	System	14 Sep 2020 23:48:08
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 23:48:08

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 7'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6fcfdf8f-0ee5-4fcd-8df8-9f71bd61e04a'	System	16 Sep 2020 13:18:24
User entered 'Yes (Y)'	System	16 Sep 2020 13:18:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:11', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6fcfdf8f-0ee5-4fcd-8df8-9f71bd61e04a'	System	16 Sep 2020 13:18:24
User entered '98.0'	System	16 Sep 2020 13:18:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:15', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6fcfdf8f-0ee5-4fcd-8df8-9f71bd61e04a'	System	16 Sep 2020 13:18:24
User entered 'No (N)'	System	16 Sep 2020 13:18:24



US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:20', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6fcfdf8f-0ee5-4fcd-8df8-9f71bd61e04a'	System	16 Sep 2020 13:18:24
User entered '16 Sep 2020 09:18'	System	16 Sep 2020 13:18:24

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'f5d8b2dd-3d94-4f19-8e44-7f08ffa82ad9'	System	09 Sep 2020 16:59:44
User entered 'None (1)'	System	09 Sep 2020 16:59:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'f5d8b2dd-3d94-4f19-8e44-7f08ffa82ad9'	System	09 Sep 2020 16:59:44
User entered 'No (N)'	System	09 Sep 2020 16:59:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:59:02', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'f5d8b2dd-3d94-4f19-8e44-7f08ffa82ad9'	System	09 Sep 2020 16:59:44
User entered 'No (N)'	System	09 Sep 2020 16:59:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:59:06', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'f5d8b2dd-3d94-4f19-8e44-7f08ffa82ad9'	System	09 Sep 2020 16:59:44
User entered 'None (1)'	System	09 Sep 2020 16:59:44



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:59:10', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'f5d8b2dd-3d94-4f19-8e44-7f08ffa82ad9'	System	09 Sep 2020 16:59:44
User entered '09 Sep 2020 12:59'	System	09 Sep 2020 16:59:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 12:38'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 15:08'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:48:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8bcc7790-0b01-4b46-b9f6-05316239ea9d'	System	10 Sep 2020 00:49:25
User entered 'None (1)'	System	10 Sep 2020 00:49:25

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:01', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8bcc7790-0b01-4b46-b9f6-05316239ea9d'	System	10 Sep 2020 00:49:25
User entered 'No (N)'	System	10 Sep 2020 00:49:25

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:05', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8bcc7790-0b01-4b46-b9f6-05316239ea9d'	System	10 Sep 2020 00:49:25
User entered 'No (N)'	System	10 Sep 2020 00:49:25

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:19', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8bcc7790-0b01-4b46-b9f6-05316239ea9d'	System	10 Sep 2020 00:49:25
User entered 'None (1)'	System	10 Sep 2020 00:49:25



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:23', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8bcc7790-0b01-4b46-b9f6-05316239ea9d'	System	10 Sep 2020 00:49:25
User entered '09 Sep 2020 20:49'	System	10 Sep 2020 00:49:25

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 2'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:13', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8555fe72-1043-4ca9-b8db-aa52dcb9a0a2'	System	10 Sep 2020 23:13:40
User entered 'None (1)'	System	10 Sep 2020 23:13:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:16', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8555fe72-1043-4ca9-b8db-aa52dcb9a0a2'	System	10 Sep 2020 23:13:40
User entered 'No (N)'	System	10 Sep 2020 23:13:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:20', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8555fe72-1043-4ca9-b8db-aa52dcb9a0a2'	System	10 Sep 2020 23:13:40
User entered 'No (N)'	System	10 Sep 2020 23:13:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:23', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8555fe72-1043-4ca9-b8db-aa52dcb9a0a2'	System	10 Sep 2020 23:13:40
User entered 'None (1)'	System	10 Sep 2020 23:13:40



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8555fe72-1043-4ca9-b8db-aa52dcb9a0a2'	System	10 Sep 2020 23:13:40
User entered '10 Sep 2020 19:13'	System	10 Sep 2020 23:13:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 3'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:46', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '03884ea1-4fd2-4a12-9ae6-7ee2d632805f'	System	11 Sep 2020 19:02:21
User entered 'None (1)'	System	11 Sep 2020 19:02:21

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:01:55', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '03884ea1-4fd2-4a12-9ae6-7ee2d632805f'	System	11 Sep 2020 19:02:21
User entered 'No (N)'	System	11 Sep 2020 19:02:21

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '03884ea1-4fd2-4a12-9ae6-7ee2d632805f'	System	11 Sep 2020 19:02:21
User entered 'No (N)'	System	11 Sep 2020 19:02:21

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '03884ea1-4fd2-4a12-9ae6-7ee2d632805f'	System	11 Sep 2020 19:02:21
User entered 'None (1)'	System	11 Sep 2020 19:02:21



**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:18', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '03884ea1-4fd2-4a12-9ae6-7ee2d632805f'	System	11 Sep 2020 19:02:21
User entered '11 Sep 2020 15:02'	System	11 Sep 2020 19:02:21

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 4'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 5'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '78f1c90f-200d-4189-a2ec-da71f8ee82d9'	System	13 Sep 2020 21:41:46
User entered 'None (1)'	System	13 Sep 2020 21:41:46

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '78f1c90f-200d-4189-a2ec-da71f8ee82d9'	System	13 Sep 2020 21:41:46
User entered 'No (N)'	System	13 Sep 2020 21:41:46



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '78f1c90f-200d-4189-a2ec-da71f8ee82d9'	System	13 Sep 2020 21:41:46
User entered 'No (N)'	System	13 Sep 2020 21:41:46

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:38', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '78f1c90f-200d-4189-a2ec-da71f8ee82d9'	System	13 Sep 2020 21:41:46
User entered 'None (1)'	System	13 Sep 2020 21:41:46

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:45', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '78f1c90f-200d-4189-a2ec-da71f8ee82d9'	System	13 Sep 2020 21:41:46
User entered '13 Sep 2020 17:41'	System	13 Sep 2020 21:41:46

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 6'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:16', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6141e8ab-d9d1-4986-9290-3e06722ca137'	System	14 Sep 2020 23:48:30
User entered 'None (1)'	System	14 Sep 2020 23:48:30

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:14', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6141e8ab-d9d1-4986-9290-3e06722ca137'	System	14 Sep 2020 23:48:30
User entered 'No (N)'	System	14 Sep 2020 23:48:30



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:19', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6141e8ab-d9d1-4986-9290-3e06722ca137'	System	14 Sep 2020 23:48:30
User entered 'No (N)'	System	14 Sep 2020 23:48:30

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:21', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6141e8ab-d9d1-4986-9290-3e06722ca137'	System	14 Sep 2020 23:48:30
User entered 'None (1)'	System	14 Sep 2020 23:48:30

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:25', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6141e8ab-d9d1-4986-9290-3e06722ca137'	System	14 Sep 2020 23:48:30
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 23:48:30

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 7'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:26', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '7ff6cc92-e035-459b-a323-5508ba71e3de'	System	16 Sep 2020 13:18:40
User entered 'None (1)'	System	16 Sep 2020 13:18:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:29', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '7ff6cc92-e035-459b-a323-5508ba71e3de'	System	16 Sep 2020 13:18:40
User entered 'No (N)'	System	16 Sep 2020 13:18:40



US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '7ff6cc92-e035-459b-a323-5508ba71e3de'	System	16 Sep 2020 13:18:40
User entered 'No (N)'	System	16 Sep 2020 13:18:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:34', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '7ff6cc92-e035-459b-a323-5508ba71e3de'	System	16 Sep 2020 13:18:40
User entered 'None (1)'	System	16 Sep 2020 13:18:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:38', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '7ff6cc92-e035-459b-a323-5508ba71e3de'	System	16 Sep 2020 13:18:40
User entered '16 Sep 2020 09:18'	System	16 Sep 2020 13:18:40

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:07', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'None (0)'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:10', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'None (0)'	System	09 Sep 2020 16:58:37



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:12', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'None (0)'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:15', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581' User entered 'None (0)'	System	09 Sep 2020 16:58:37
	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:17', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'None (0)'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:19', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'None (0)'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:22', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered 'No (N)'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T12:58:33', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8df04954-1fb0-47d3-8a00-614d1ef23581'	System	09 Sep 2020 16:58:37
User entered '09 Sep 2020 12:58'	System	09 Sep 2020 16:58:37

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 12:38'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 15:08'	System	09 Sep 2020 16:56:44



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:30', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:34', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:38', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:40', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'None (0)'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:48', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered 'No (N)'	System	10 Sep 2020 00:49:55



**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-09T20:49:51', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '39afde47-8d11-410b-b58c-7e95e75d079b'	System	10 Sep 2020 00:49:55
User entered '09 Sep 2020 20:49'	System	10 Sep 2020 00:49:55

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 2'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:33', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:35', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:37', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'None (0)'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:44', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered 'No (N)'	System	10 Sep 2020 23:13:50

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-10T19:13:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a13e1f6d-b4d7-43e9-93b6-cec2415abee0'	System	10 Sep 2020 23:13:50
User entered '10 Sep 2020 19:13'	System	10 Sep 2020 23:13:50

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 3'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:22', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47



**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:24', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:25', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:29', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'None (0)'	System	11 Sep 2020 19:02:47

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered 'No (N)'	System	11 Sep 2020 19:02:47

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-11T15:02:42', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6e0d4a37-2d99-4c80-89ba-585ed27dd3de'	System	11 Sep 2020 19:02:47
User entered '11 Sep 2020 15:02'	System	11 Sep 2020 19:02:47

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:56:44



**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 4'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 5'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:50', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:52', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:56', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:41:58', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:42:01', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'None (0)'	System	13 Sep 2020 21:42:11

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:42:06', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered 'No (N)'	System	13 Sep 2020 21:42:11

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-13T17:42:09', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c43ea8d1-6903-439a-9717-3b38fa22b813'	System	13 Sep 2020 21:42:11
User entered '13 Sep 2020 17:42'	System	13 Sep 2020 21:42:11

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 6'	System	09 Sep 2020 16:56:44



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:30', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:33', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:35', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:44', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'None (0)'	System	14 Sep 2020 23:48:54

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:49', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered 'No (N)'	System	14 Sep 2020 23:48:54

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-14T19:48:52', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '55626051-1fc4-4911-9d15-51e8e95085c8'	System	14 Sep 2020 23:48:54
User entered '14 Sep 2020 19:48'	System	14 Sep 2020 23:48:54



US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 7'	System	09 Sep 2020 16:56:44

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:43', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:45', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:49', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:51', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04



**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:53', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'None (0)'	System	16 Sep 2020 13:19:04

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:56', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered 'No (N)'	System	16 Sep 2020 13:19:04

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97d98d9b1df9f148)', Time: '2020-09-16T09:18:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ad7e47-70a6-4246-a726-56919295e80a'	System	16 Sep 2020 13:19:04
User entered '16 Sep 2020 09:18'	System	16 Sep 2020 13:19:04

US3802185

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:56:44

**US3802185**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:30:43

US3802185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '18 Sep 2020'	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:30:43

US3802185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	Dominic Kramer (b) (4) (b) (4)	18 Sep 2020 18:30:43



**US3802185**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:30:43

US3802185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	18 Sep 2020 18:30:49

**US3802185**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	18 Sep 2020 18:30:49

**US3802185**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	23 Sep 2020 17:57:07

**US3802185**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '23 Sep 2020'	(b) (4) Lalicia Roman (b) (4)	23 Sep 2020 17:57:07

US3802185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4)	23 Sep 2020 17:57:07

**US3802185**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	23 Sep 2020 17:57:07

US3802185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	23 Sep 2020 17:57:12



**US3802185**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	23 Sep 2020 17:57:12

**US3802185**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	01 Oct 2020 17:12:59

US3802185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '1 Oct 2020'	(b) (4) Jennifer Nagg (b) (4)	01 Oct 2020 17:12:59

US3802185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Nagg (b) (4)	01 Oct 2020 17:12:59

**US3802185**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Jennifer Nagg (b) (4)	01 Oct 2020 17:12:59

US3802185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	01 Oct 2020 17:13:05

US3802185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	01 Oct 2020 17:13:05

US3802185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:09



US3802185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:09

US3802185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:25:09

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'VISIT2'	System	12 Oct 2020 20:25:09

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Pre-Dose (PREDOSE)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '15:11'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '12 Oct 2020 15:11'	System	12 Oct 2020 20:34:06



US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '97.9' F	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '102'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'bpm'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '18'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'breaths/min'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '133'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06



US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	12 Oct 2020 20:34:06

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '88'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Post-Dose (POSTDOSE)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User closed query 'Per CDM: The treatment time on the Exposure CRF is 15:58 and the Vital Signs Post Dose Time of Assessment is 16:27 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed	(b) (4) (b) (4), (b) (6)	30 Oct 2020 14:12:39
' (Site from DM). Query 'Per CDM: The treatment time on the Exposure CRF is 15:58 and the Vital Signs Post Dose Time of Assessment is 16:27 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed	Jennifer Nagg (b) (4)	19 Oct 2020 18:44:27
' answered with 'done' (Site from DM). User entered '16:29' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Oct 2020 18:44:19
User opened query 'Per CDM: The treatment time on the Exposure CRF is 15:58 and the Vital Signs Post Dose Time of Assessment is 16:27 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed	(b) (4), (b) (6)	19 Oct 2020 13:34:52
' (Site from DM). User entered '16:27'	Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '12 Oct 2020 16:29'	System	19 Oct 2020 18:44:19
User entered '12 Oct 2020 16:27'	System	12 Oct 2020 20:34:06



US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '97.1' F	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '96'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'bpm'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '18'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'breaths/min'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '133'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06



US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '87'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	12 Oct 2020 20:34:06

US3802185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:15

US3802185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:25:15

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25
	(b) (4)	

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Urine (URINE)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25



US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Negative (NEGATIVE)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25

US3802185

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:25:25

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered empty.	System	12 Oct 2020 20:25:25

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

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)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:26:02



US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '15:58'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '12 Oct 2020 15:58'	System	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'ONCE'	System	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 20:26:02

US3802185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:23



US3802185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:23

US3802185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '15:51'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:23

US3802185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '12 Oct 2020 15:51'	System	12 Oct 2020 20:26:23

US3802185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '12 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:36

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:26:36

US3802185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:36

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '15:52'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:36

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '12 Oct 2020 15:52'	System	12 Oct 2020 20:26:36



**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:26:36

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:36

US3802185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:26:36

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered empty.	System	12 Oct 2020 20:26:36

US3802185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:26:41

**US3802185**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	12 Oct 2020 20:26:41

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:29:56', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5f57dbb-0726-4fd2-a3ef-6a608aeebd6b'	System	12 Oct 2020 20:30:34
User entered 'Yes (Y)'	System	12 Oct 2020 20:30:34



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:02', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5f57dbb-0726-4fd2-a3ef-6a608aeebd6b'	System	12 Oct 2020 20:30:34
User entered '97.7'	System	12 Oct 2020 20:30:34

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:21', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5f57dbb-0726-4fd2-a3ef-6a608aeebd6b'	System	12 Oct 2020 20:30:34
User entered 'No (N)'	System	12 Oct 2020 20:30:34

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5f57dbb-0726-4fd2-a3ef-6a608aeebd6b'	System	12 Oct 2020 20:30:34
User entered '12 Oct 2020 16:30'	System	12 Oct 2020 20:30:34

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 16:18'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 18:48'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:31:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8c4d2cce-196c-4f81-8945-8db53f98cc50'	System	13 Oct 2020 12:32:13
User entered 'Yes (Y)'	System	13 Oct 2020 12:32:13

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8c4d2cce-196c-4f81-8945-8db53f98cc50'	System	13 Oct 2020 12:32:13
User entered '98.3'	System	13 Oct 2020 12:32:13



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8c4d2cce-196c-4f81-8945-8db53f98cc50'	System	13 Oct 2020 12:32:13
User entered 'No (N)'	System	13 Oct 2020 12:32:13

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:08', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8c4d2cce-196c-4f81-8945-8db53f98cc50'	System	13 Oct 2020 12:32:13
User entered '13 Oct 2020 08:32'	System	13 Oct 2020 12:32:13

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 19:43'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 2'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:20', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '16f02313-e016-4ee9-aa09-a689386f5b21'	System	13 Oct 2020 19:23:39
User entered 'Yes (Y)'	System	13 Oct 2020 19:23:39

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:26', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '16f02313-e016-4ee9-aa09-a689386f5b21'	System	13 Oct 2020 19:23:39
User entered '98.2'	System	13 Oct 2020 19:23:39

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:29', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '16f02313-e016-4ee9-aa09-a689386f5b21'	System	13 Oct 2020 19:23:39
User entered 'No (N)'	System	13 Oct 2020 19:23:39



**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:34', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '16f02313-e016-4ee9-aa09-a689386f5b21'	System	13 Oct 2020 19:23:39
User entered '13 Oct 2020 15:23'	System	13 Oct 2020 19:23:39

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 3'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9a4ec7bb-7dea-4645-984e-7fd10a7b4c7d'	System	15 Oct 2020 14:38:50
User entered 'Yes (Y)'	System	15 Oct 2020 14:38:50

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:38', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9a4ec7bb-7dea-4645-984e-7fd10a7b4c7d'	System	15 Oct 2020 14:38:50
User entered '98.1'	System	15 Oct 2020 14:38:50

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9a4ec7bb-7dea-4645-984e-7fd10a7b4c7d'	System	15 Oct 2020 14:38:50
User entered 'No (N)'	System	15 Oct 2020 14:38:50

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:44', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9a4ec7bb-7dea-4645-984e-7fd10a7b4c7d'	System	15 Oct 2020 14:38:50
User entered '15 Oct 2020 10:38'	System	15 Oct 2020 14:38:50



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 4'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 5'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:12:57', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c5d8354e-91fb-4015-b957-87bbdd08c343'	System	16 Oct 2020 21:13:18
User entered 'Yes (Y)'	System	16 Oct 2020 21:13:18

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:02', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c5d8354e-91fb-4015-b957-87bbdd08c343'	System	16 Oct 2020 21:13:18
User entered '99.1'	System	16 Oct 2020 21:13:18

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:07', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c5d8354e-91fb-4015-b957-87bddd08c343'	System	16 Oct 2020 21:13:18
User entered 'No (N)'	System	16 Oct 2020 21:13:18

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:11', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c5d8354e-91fb-4015-b957-87bddd08c343'	System	16 Oct 2020 21:13:18
User entered '16 Oct 2020 17:13'	System	16 Oct 2020 21:13:18



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 6'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:21', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9e24da5b-8803-4a65-8a59-52957506e9b3'	System	18 Oct 2020 01:39:45
User entered 'Yes (Y)'	System	18 Oct 2020 01:39:45

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9e24da5b-8803-4a65-8a59-52957506e9b3'	System	18 Oct 2020 01:39:45
User entered '97.7'	System	18 Oct 2020 01:39:45

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9e24da5b-8803-4a65-8a59-52957506e9b3'	System	18 Oct 2020 01:39:45
User entered 'No (N)'	System	18 Oct 2020 01:39:45

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:40', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9e24da5b-8803-4a65-8a59-52957506e9b3'	System	18 Oct 2020 01:39:45
User entered '17 Oct 2020 21:39'	System	18 Oct 2020 01:39:45

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 7'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:25:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63f75188-305e-4bcb-bed2-12a2af94e606'	System	18 Oct 2020 23:26:10
User entered 'Yes (Y)'	System	18 Oct 2020 23:26:10

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:25:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63f75188-305e-4bcb-bed2-12a2af94e606'	System	18 Oct 2020 23:26:10
User entered '98.4'	System	18 Oct 2020 23:26:10

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:02', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63f75188-305e-4bcb-bed2-12a2af94e606'	System	18 Oct 2020 23:26:10
User entered 'No (N)'	System	18 Oct 2020 23:26:10

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:05', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63f75188-305e-4bcb-bed2-12a2af94e606'	System	18 Oct 2020 23:26:10
User entered '18 Oct 2020 19:26'	System	18 Oct 2020 23:26:10

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:40', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9709c582-a7a9-4e9b-bdb0-2a92d65f95e0'	System	12 Oct 2020 20:30:58
User entered 'None (1)'	System	12 Oct 2020 20:30:58

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:43', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9709c582-a7a9-4e9b-bdb0-2a92d65f95e0'	System	12 Oct 2020 20:30:58
User entered 'No (N)'	System	12 Oct 2020 20:30:58

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:46', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9709c582-a7a9-4e9b-bdb0-2a92d65f95e0'	System	12 Oct 2020 20:30:58
User entered 'No (N)'	System	12 Oct 2020 20:30:58

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:50', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9709c582-a7a9-4e9b-bdb0-2a92d65f95e0'	System	12 Oct 2020 20:30:58
User entered 'None (1)'	System	12 Oct 2020 20:30:58

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:30:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9709c582-a7a9-4e9b-bdb0-2a92d65f95e0'	System	12 Oct 2020 20:30:58
User entered '12 Oct 2020 16:30'	System	12 Oct 2020 20:30:58

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 16:18'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 18:48'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:14', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63398164-e93a-454a-aaf7-d1127533781e'	System	13 Oct 2020 12:32:40
User entered 'None (1)'	System	13 Oct 2020 12:32:40

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:17', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63398164-e93a-454a-aaf7-d1127533781e'	System	13 Oct 2020 12:32:40
User entered 'No (N)'	System	13 Oct 2020 12:32:40

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:26', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63398164-e93a-454a-aaf7-d1127533781e'	System	13 Oct 2020 12:32:40
User entered 'No (N)'	System	13 Oct 2020 12:32:40

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:29', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63398164-e93a-454a-aaf7-d1127533781e'	System	13 Oct 2020 12:32:40
User entered 'None (1)'	System	13 Oct 2020 12:32:40

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '63398164-e93a-454a-aaf7-d1127533781e'	System	13 Oct 2020 12:32:40
User entered '13 Oct 2020 08:32'	System	13 Oct 2020 12:32:40

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 19:43'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 2'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5cc759d9-842a-4255-8d70-a576231fe04c'	System	13 Oct 2020 19:23:57
User entered 'None (1)'	System	13 Oct 2020 19:23:57

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:42', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5cc759d9-842a-4255-8d70-a576231fe04c'	System	13 Oct 2020 19:23:57
User entered 'No (N)'	System	13 Oct 2020 19:23:57

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:46', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5cc759d9-842a-4255-8d70-a576231fe04c'	System	13 Oct 2020 19:23:57
User entered 'No (N)'	System	13 Oct 2020 19:23:57

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:50', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5cc759d9-842a-4255-8d70-a576231fe04c'	System	13 Oct 2020 19:23:57
User entered 'None (1)'	System	13 Oct 2020 19:23:57

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:52', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5cc759d9-842a-4255-8d70-a576231fe04c'	System	13 Oct 2020 19:23:57
User entered '13 Oct 2020 15:23'	System	13 Oct 2020 19:23:57

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 3'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:49', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '748f6d77-a409-42c5-8d57-8257f6c472d3'	System	15 Oct 2020 14:39:24
User entered 'None (1)'	System	15 Oct 2020 14:39:24

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:38:57', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '748f6d77-a409-42c5-8d57-8257f6c472d3'	System	15 Oct 2020 14:39:24
User entered 'No (N)'	System	15 Oct 2020 14:39:24

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:12', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '748f6d77-a409-42c5-8d57-8257f6c472d3'	System	15 Oct 2020 14:39:24
User entered 'No (N)'	System	15 Oct 2020 14:39:24

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:14', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '748f6d77-a409-42c5-8d57-8257f6c472d3'	System	15 Oct 2020 14:39:24
User entered 'None (1)'	System	15 Oct 2020 14:39:24

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:18', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '748f6d77-a409-42c5-8d57-8257f6c472d3'	System	15 Oct 2020 14:39:24
User entered '15 Oct 2020 10:39'	System	15 Oct 2020 14:39:24

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 4'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 5'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:20', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9b8c89f3-6858-40c7-b058-e096daa95a2e'	System	16 Oct 2020 21:13:39
User entered 'None (1)'	System	16 Oct 2020 21:13:39

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:23', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9b8c89f3-6858-40c7-b058-e096daa95a2e'	System	16 Oct 2020 21:13:39
User entered 'No (N)'	System	16 Oct 2020 21:13:39

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9b8c89f3-6858-40c7-b058-e096daa95a2e'	System	16 Oct 2020 21:13:39
User entered 'No (N)'	System	16 Oct 2020 21:13:39

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:30', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9b8c89f3-6858-40c7-b058-e096daa95a2e'	System	16 Oct 2020 21:13:39
User entered 'None (1)'	System	16 Oct 2020 21:13:39

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9b8c89f3-6858-40c7-b058-e096daa95a2e'	System	16 Oct 2020 21:13:39
User entered '16 Oct 2020 17:13'	System	16 Oct 2020 21:13:39



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 6'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:48', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9d6c16d9-9b9d-4a33-a6ba-77c9ef460663'	System	18 Oct 2020 01:40:06
User entered 'None (1)'	System	18 Oct 2020 01:40:06

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:51', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9d6c16d9-9b9d-4a33-a6ba-77c9ef460663'	System	18 Oct 2020 01:40:06
User entered 'No (N)'	System	18 Oct 2020 01:40:06

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:54', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9d6c16d9-9b9d-4a33-a6ba-77c9ef460663'	System	18 Oct 2020 01:40:06
User entered 'No (N)'	System	18 Oct 2020 01:40:06

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:57', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9d6c16d9-9b9d-4a33-a6ba-77c9ef460663'	System	18 Oct 2020 01:40:06
User entered 'None (1)'	System	18 Oct 2020 01:40:06

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:39:59', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '9d6c16d9-9b9d-4a33-a6ba-77c9ef460663'	System	18 Oct 2020 01:40:06
User entered '17 Oct 2020 21:39'	System	18 Oct 2020 01:40:06



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 7'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:10', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ceee04-c1b2-4a76-94f3-ce7b2a94e6ce'	System	18 Oct 2020 23:26:30
User entered 'None (1)'	System	18 Oct 2020 23:26:30

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:13', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ceee04-c1b2-4a76-94f3-ce7b2a94e6ce'	System	18 Oct 2020 23:26:30
User entered 'No (N)'	System	18 Oct 2020 23:26:30

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:22', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ceee04-c1b2-4a76-94f3-ce7b2a94e6ce'	System	18 Oct 2020 23:26:30
User entered 'No (N)'	System	18 Oct 2020 23:26:30

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:24', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ceee04-c1b2-4a76-94f3-ce7b2a94e6ce'	System	18 Oct 2020 23:26:30
User entered 'None (1)'	System	18 Oct 2020 23:26:30

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:27', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b5ceee04-c1b2-4a76-94f3-ce7b2a94e6ce'	System	18 Oct 2020 23:26:30
User entered '18 Oct 2020 19:26'	System	18 Oct 2020 23:26:30



US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:01', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:09', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:12', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:14', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:16', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'None (0)'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:22', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered 'No (N)'	System	12 Oct 2020 20:31:30

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-12T16:31:24', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b8769357-d258-42c5-8f43-809047c7507b'	System	12 Oct 2020 20:31:30
User entered '12 Oct 2020 16:31'	System	12 Oct 2020 20:31:30

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 16:18'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 18:48'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:43', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:45', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'None (0)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:50', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered 'No (N)'	System	13 Oct 2020 12:32:58

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T08:32:52', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ab59ed51-9924-46da-b5bf-d791de396e1f'	System	13 Oct 2020 12:32:58
User entered '13 Oct 2020 08:32'	System	13 Oct 2020 12:32:58

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '12 Oct 2020 19:43'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 2'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:56', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:23:58', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:02', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:06', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'None (0)'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:08', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered 'No (N)'	System	13 Oct 2020 19:24:15



**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-13T15:24:10', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '3746081b-9ed8-458f-8ae3-48caad04bd02'	System	13 Oct 2020 19:24:15
User entered '13 Oct 2020 15:24'	System	13 Oct 2020 19:24:15

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:31:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 3'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:22', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:24', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:26', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:28', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:30', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:32', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'None (0)'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:34', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered 'No (N)'	System	15 Oct 2020 14:39:43

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-15T10:39:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '5027c306-3a3c-4785-938f-5127542548c5'	System	15 Oct 2020 14:39:43
User entered '15 Oct 2020 10:39'	System	15 Oct 2020 14:39:43

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 4'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 20:26:02



**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 5'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:38', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:43', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:45', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:47', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'None (0)'	System	16 Oct 2020 21:13:57



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:49', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered 'No (N)'	System	16 Oct 2020 21:13:57

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-16T17:13:52', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '07d0fd5d-97e6-46a2-ad15-2012f971b342'	System	16 Oct 2020 21:13:57
User entered '16 Oct 2020 17:13'	System	16 Oct 2020 21:13:57

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 6'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:04', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:06', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:08', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:10', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:12', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:13', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'None (0)'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:16', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered 'No (N)'	System	18 Oct 2020 01:40:23

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-17T21:40:18', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'bd42e7ab-9100-4bff-b042-82ce7b1e9c7d'	System	18 Oct 2020 01:40:23
User entered '17 Oct 2020 21:40'	System	18 Oct 2020 01:40:23

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:31:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
Data entry locked.	System	12 Oct 2020 20:26:02
User entered 'Day 7'	System	12 Oct 2020 20:26:02



US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:31', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:33', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:35', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:36', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:39', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:41', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'None (0)'	System	18 Oct 2020 23:26:47

US3802185

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:31:00

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 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:43', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered 'No (N)'	System	18 Oct 2020 23:26:47

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2020-10-18T19:26:45', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '954ee390-ea6d-4a7b-b380-6f7e34b5e306'	System	18 Oct 2020 23:26:47
User entered '18 Oct 2020 19:26'	System	18 Oct 2020 23:26:47



**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 20:26:02

**US3802185**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:31:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:23:49
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 20:26:02

**US3802185**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	19 Oct 2020 13:56:54

US3802185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '19 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	19 Oct 2020 13:56:54
	(b) (4)	

US3802185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4)	19 Oct 2020 13:56:54

**US3802185**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	19 Oct 2020 13:56:54

US3802185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	19 Oct 2020 13:56:59

**US3802185**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	19 Oct 2020 13:56:59



**US3802185**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Oct 2020 18:06:20

**US3802185**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '26 Oct 2020'	(b) (4) Lalicia Roman (b) (4)	26 Oct 2020 18:06:20

US3802185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4)	26 Oct 2020 18:06:20

**US3802185**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	26 Oct 2020 18:06:20

US3802185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	26 Oct 2020 18:06:24

**US3802185**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	26 Oct 2020 18:06:24

**US3802185**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Nov 2020 19:26:20

**US3802185**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '3 Nov 2020'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Nov 2020 19:26:20



US3802185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lalicia Roman (b) (4)	03 Nov 2020 19:26:20

**US3802185**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Nov 2020 19:26:20

US3802185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	03 Nov 2020 19:26:27

**US3802185**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	03 Nov 2020 19:26:27

US3802185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User closed query 'Per CDM: Please complete Physical Examination form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:13:06
Query 'Per CDM: Please complete Physical Examination form. Thank you.' answered with 'completed' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:59:32
User opened query 'Per CDM: Please complete Physical Examination form. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:52:48
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:16:19

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '11 Nov 2020'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:19

US3802185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:16:19

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'VISIT3'	System	11 Nov 2020 20:16:19



US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '11 Nov 2020'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '14:53'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '11 Nov 2020 14:53'	System	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '36' C	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:16:59

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '95'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59



**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'bpm'	System	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '20'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'breaths/min'	System	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '126'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:16:59

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '83'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:16:59

**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'mmHg'	System	11 Nov 2020 20:16:59

US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34



US3802185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34

US3802185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 13:59:10

US3802185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '11 Nov 2020'	(b) (4) Jennifer Nagg (b) (4)	24 Nov 2020 13:59:10

US3802185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:17:18

US3802185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '11 Nov 2020'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:17:18

US3802185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered '14:58'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:17:18

US3802185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered '11 Nov 2020 14:58'	System	11 Nov 2020 20:17:18

US3802185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:59
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Nov 2020 20:17:22



**US3802185**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	11 Nov 2020 20:17:22

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 64'	System	09 Sep 2020 16:56:44

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

Have you been exposed to someone with 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 16:56:44

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 16:56:44

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered 'Day 71'	System	09 Sep 2020 16:56:44

US3802185

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

Have you been exposed to someone with 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

US3802185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:31:00

[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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Please 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 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 16:56:44



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:35:40
Data entry locked.	System	09 Sep 2020 16:56:44
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 16:56:44

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-03-02T21:44:00-05:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8ec1571f-df6c-4b72-8f74-760fa800ac87'	System	03 Mar 2021 02:45:23
User entered 'No (N)'	System	03 Mar 2021 02:45:23

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-03-02T21:44:09-05:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8ec1571f-df6c-4b72-8f74-760fa800ac87'	System	03 Mar 2021 02:45:23
User entered 'No (N)'	System	03 Mar 2021 02:45:23

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-02T21:44:16-05:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '8ec1571f-df6c-4b72-8f74-760fa800ac87'	System	03 Mar 2021 02:45:23
User entered '02 Mar 2021 21:44:16'	System	03 Mar 2021 02:45:23

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-03-15T16:38:12-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '88099614-4a91-4e4f-95c0-355656b69570'	System	15 Mar 2021 20:38:29
User entered 'No (N)'	System	15 Mar 2021 20:38:29

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-03-15T16:38:21-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '88099614-4a91-4e4f-95c0-355656b69570'	System	15 Mar 2021 20:38:29
User entered 'No (N)'	System	15 Mar 2021 20:38:29

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-15T16:38:25-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '88099614-4a91-4e4f-95c0-355656b69570'	System	15 Mar 2021 20:38:29
User entered '15 Mar 2021 16:38:25'	System	15 Mar 2021 20:38:29



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-03-23T16:11:11-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b885c753-5b8a-40e7-a0f0-616adc133619'	System	23 Mar 2021 20:11:27
User entered 'No (N)'	System	23 Mar 2021 20:11:27

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-03-23T16:11:17-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b885c753-5b8a-40e7-a0f0-616adc133619'	System	23 Mar 2021 20:11:27
User entered 'No (N)'	System	23 Mar 2021 20:11:27

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-23T16:11:20-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'b885c753-5b8a-40e7-a0f0-616adc133619'	System	23 Mar 2021 20:11:27
User entered '23 Mar 2021 16:11:20'	System	23 Mar 2021 20:11:27

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-03-30T13:07:42-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '37789a2b-536b-45db-b9a1-b85a1ec1ca30'	System	30 Mar 2021 17:10:38
User entered 'No (N)'	System	30 Mar 2021 17:10:38

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-03-30T13:07:45-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '37789a2b-536b-45db-b9a1-b85a1ec1ca30'	System	30 Mar 2021 17:10:38
User entered 'No (N)'	System	30 Mar 2021 17:10:38

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-30T13:07:48-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '37789a2b-536b-45db-b9a1-b85a1ec1ca30' User entered '30 Mar 2021 13:07:48'	System	30 Mar 2021 17:10:38
	System	30 Mar 2021 17:10:38

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-04-06T18:21:43-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6a849a18-c620-4497-a18d-f96971784235' User entered 'No (N)'	System	06 Apr 2021 22:25:12
	System	06 Apr 2021 22:25:12



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-04-06T18:21:48-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6a849a18-c620-4497-a18d-f96971784235'	System	06 Apr 2021 22:25:12
User entered 'No (N)'	System	06 Apr 2021 22:25:12

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-04-06T18:21:52-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '6a849a18-c620-4497-a18d-f96971784235' User entered '06 Apr 2021 18:21:52'	System	06 Apr 2021 22:25:12
	System	06 Apr 2021 22:25:12

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-04-12T13:12:16-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '1e987b41-0028-4d7d-9bbd-713d671b7953' User entered 'No (N)'	System	12 Apr 2021 17:18:54

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-04-12T13:12:18-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '1e987b41-0028-4d7d-9bbd-713d671b7953'	System	12 Apr 2021 17:18:54
User entered 'No (N)'	System	12 Apr 2021 17:18:54

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-04-12T13:12:21-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '1e987b41-0028-4d7d-9bbd-713d671b7953'	System	12 Apr 2021 17:18:54
User entered '12 Apr 2021 13:12:21'	System	12 Apr 2021 17:18:54



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-04-20T11:18:45-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ff1b5216-4773-4239-a50b-c565d95d775b' User entered 'No (N)'	System	20 Apr 2021 15:18:54
	System	20 Apr 2021 15:18:54

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-04-20T11:18:48-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ff1b5216-4773-4239-a50b-c565d95d775b'	System	20 Apr 2021 15:18:54
User entered 'No (N)'	System	20 Apr 2021 15:18:54

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-04-20T11:18:51-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'ff1b5216-4773-4239-a50b-c565d95d775b'	System	20 Apr 2021 15:18:54
User entered '20 Apr 2021 11:18:51'	System	20 Apr 2021 15:18:54

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-04-25T15:51:35-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c46974aa-638a-4f68-91d1-da0650466b4c' User entered 'No (N)'	System	25 Apr 2021 19:51:46
	System	25 Apr 2021 19:51:46

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-04-25T15:51:40-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c46974aa-638a-4f68-91d1-da0650466b4c'	System	25 Apr 2021 19:51:46
User entered 'No (N)'	System	25 Apr 2021 19:51:46

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-04-25T15:51:43-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'c46974aa-638a-4f68-91d1-da0650466b4c'	System	25 Apr 2021 19:51:46
User entered '25 Apr 2021 15:51:43'	System	25 Apr 2021 19:51:46

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[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 (f007a019ce9ae91e)', Time: '2021-04-30T00:16:34-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '26656bb5-29fe-46da-bf4d-4b1b3b18ebd6' User entered 'No (N)'	System	30 Apr 2021 04:16:44
	System	30 Apr 2021 04:16:44



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

Have you been exposed to someone with 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 (f007a019ce9ae91e)', Time: '2021-04-30T00:16:38-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '26656bb5-29fe-46da-bf4d-4b1b3b18ebd6'	System	30 Apr 2021 04:16:44
User entered 'No (N)'	System	30 Apr 2021 04:16:44

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-04-30T00:16:41-04:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: '26656bb5-29fe-46da-bf4d-4b1b3b18ebd6'	System	30 Apr 2021 04:16:44
User entered '30 Apr 2021 00:16:41'	System	30 Apr 2021 04:16:44

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:35:40



**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:35:40



**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:35:40

**US3802185**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:31:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:35:40
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:35:40

US3802185

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:31:00**

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 19:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-02T21:43:39-05:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a6b32b83-fb6c-49b1-a1a2-d8616b435fa1'	System	03 Mar 2021 02:44:59
User entered 'No (N)'	System	03 Mar 2021 02:44:59

**US3802185**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f007a019ce9ae91e)', Time: '2021-03-02T21:43:49-05:00', User OID: 'PatientReportedOutcome (US3802185)', ODM File OID: 'a6b32b83-fb6c-49b1-a1a2-d8616b435fa1'	System	03 Mar 2021 02:44:59
User entered '02 Mar 2021 21:43:49'	System	03 Mar 2021 02:44:59

**US3802185**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	08 Dec 2020 18:03:02

US3802185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Dec 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	08 Dec 2020 18:03:02



US3802185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Fries (b) (4) (b) (4)	08 Dec 2020 18:03:02

**US3802185**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Jamie Fries (b) (4) (b) (4)	08 Dec 2020 18:03:02

US3802185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	08 Dec 2020 18:03:52

**US3802185**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:15:34
User entered 'I'	System	08 Dec 2020 18:03:52

**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4)	27 Jan 2021 18:32:00

**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12 Jan 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	27 Jan 2021 18:32:00

**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	27 Jan 2021 18:32:00

**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	27 Jan 2021 18:32:00



**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Emily Carney (b) (4) (b) (4)	27 Jan 2021 18:31:33

**US3802185**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'I'	System	27 Jan 2021 18:31:33

**US3802185**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:41

**US3802185**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '9 Feb 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:41

US3802185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:41

**US3802185**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:41

US3802185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:45

**US3802185**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'I'	System	09 Feb 2021 14:42:45



**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Mar 2021 15:25:52

**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '9 Mar 2021'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Mar 2021 15:25:52

**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Mar 2021 15:25:52

**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered empty.	(b) (4) Emily Carney (b) (4) (b) (4)	09 Mar 2021 15:25:52

**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Mar 2021 15:25:45

**US3802185**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'I'	System	09 Mar 2021 15:25:45

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:59:15

US3802185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		17 Mar 2021 09:53:40
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'combined visit date falls within the participant's window' (Site from System).	(b) (4)	
	Lalicia Roman (b) (4)	11 Mar 2021 15:59:40
	(b) (4)	
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	11 Mar 2021 15:59:15
User entered '11 Mar 2021'	Lalicia Roman (b) (4)	11 Mar 2021 15:59:15
	(b) (4)	



US3802185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[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 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Mar 2021 15:59:15

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'VISIT4'	System	11 Mar 2021 15:59:15

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered 'Yes (Y)'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '11 Mar 2021'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '08:41'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered '11 Mar 2021 08:41'	System	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '99.6' F	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered 'Other (Other)'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22



US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered 'infrared'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '83'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'bpm'	System	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '18'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'breaths/min'	System	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '103'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'mmHg'	System	31 Mar 2021 13:44:22

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
User entered '71'	(b) (4) Jamie Fries (b) (4) (b) (4)	31 Mar 2021 13:44:22



**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'mmHg'	System	31 Mar 2021 13:44:22

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15

US3802185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15

US3802185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
	(b) (4)	
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Mar 2021 15:59:56
	(b) (4)	

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:59:56

US3802185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 16:00:15
	(b) (4)	

US3802185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '11 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 16:00:15
	(b) (4)	

US3802185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '08:45'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 16:00:15



US3802185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered '11 Mar 2021 08:45'	System	11 Mar 2021 16:00:15

US3802185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 16:00:20

**US3802185**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:27:15
User entered 'I'	System	11 Mar 2021 16:00:20

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:00

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:20:34
User entered '11 Nov 2020'	Lalicia Roman (b) (4)	11 Nov 2020 20:18:41

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:00

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:20:34
User entered '14:53'	Lalicia Roman (b) (4)	11 Nov 2020 20:18:41

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:00

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:51
User entered '11 Nov 2020 14:53'	System	11 Nov 2020 20:18:41

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:00

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:51
DataPoint Verified.		17 Feb 2021 17:19:36
User closed query 'Per ETRTR: Visit 3 Day57 was completed on the same day. Please consider to update the Type of Contact to " Clinical Visit -Scheduled", otherwise please clarify.' (Site from CRA).		17 Feb 2021 17:19:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Query 'Per ETRTR: Visit 3 Day57 was completed on the same day. Please consider to update the Type of Contact to " Clinical Visit -Scheduled", otherwise please clarify.' answered with 'updated' (Site from CRA).	Jennifer Nagg (b) (4)	10 Jan 2021 11:17:26
DataPoint Un-verified.	Jennifer Nagg (b) (4)	10 Jan 2021 11:17:20
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	10 Jan 2021 11:17:20
User opened query 'Per ETRTR: Visit 3 Day57 was completed on the same day. Please consider to update the Type of Contact to " Clinical Visit -Scheduled", otherwise please clarify.' (Site from CRA).	(b) (4), (b) (6)	26 Nov 2020 20:42:07
DataPoint Verified.		17 Nov 2020 20:20:34
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Lalicia Roman (b) (4)	11 Nov 2020 20:18:41

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:31:00

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:20:34
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Nov 2020 20:18:41



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 1 (Day 1)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:31
User entered '11 Nov 2020'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:32
User entered '0'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:49:46
Query 'Source does not have O2 Sat value for Day 1 -11Nov2020. Please verify and update.' canceled (Site from CRA).		17 Nov 2020 20:49:44
User opened query 'Source does not have O2 Sat value for Day 1 -11Nov2020. Please verify and update.' (Site from CRA).		17 Nov 2020 20:28:39
User entered '97'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:34
User entered '36' C	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:35
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:38
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:40
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:42
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:43
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:52
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:54
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:02
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:01
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:00
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:58
User entered 'Moderate (Moderate)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:04
User entered 'Moderate (Moderate)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:06
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:07
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:09
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:10
User entered 'None (None)'	Lalicia Roman (b) (4)	11 Nov 2020 20:19:58

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 2 (Day 2)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:33
User entered '12 Nov 2020'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:34
User entered '0'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:36
User entered '97'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:37
User entered '98.7' F	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:38
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:40
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:42
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:43
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:45
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:47
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:49
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:50
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:52
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:54
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:25:49
User closed query 'As per source Symptom Log 12Nov2020, Nasal congestion is listed as Mild. Please verify and update this entry.' (Site from CRA). Query 'As per source Symptom Log 12Nov2020, Nasal congestion is listed as Mild. Please verify and update this entry.' answered with 'confirmed with source and updated entry' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:25:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	19 Nov 2020 17:51:50
User opened query 'As per source Symptom Log 12Nov2020, Nasal congestion is listed as Mild. Please verify and update this entry.' (Site from CRA).	(b) (4)	19 Nov 2020 17:51:30
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 20:41:23
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:40:17
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 20:39:55
	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:57
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:39:59
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:40:01
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:40:03
User entered 'None (None)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:40:05
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:21:25

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'The source Symptom log for Day 3-13Nov 2020 in not available for verification. Please update the subject chart.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:03:57
Query 'The source Symptom log for Day 3-13Nov 2020 in not available for verification. Please update the subject chart.' answered with 'updated subject chart' (Site from CRA).	Emily Dougherty (b) (4)	19 Nov 2020 17:52:18
User opened query 'The source Symptom log for Day 3-13Nov 2020 in not available for verification. Please update the subject chart.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:33:49
Query 'Source for Day 3- 03 Nov2020 Symptom log is not available to verify.' canceled (Site from CRA).		17 Nov 2020 20:33:34
User opened query 'Source for Day 3- 03 Nov2020 Symptom log is not available to verify.' (Site from CRA).		17 Nov 2020 20:32:02
User entered 'Day 3 (Day 3)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '13 Nov 2020'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:04:14
User entered '95'	Emily Carney (b) (4)	16 Nov 2020 15:48:26



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:04:16
User entered '99.5' F	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:04:19
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:48:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'The source Symptom log for Day 4-14 Nov 2020 in not available for verification. Please update the subject chart.' (Site from CRA). Query 'The source Symptom log for Day 4-14 Nov 2020 in not available for verification. Please update the subject chart.' answered with 'updated subject chart' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:17:49
User opened query 'The source Symptom log for Day 4-14 Nov 2020 in not available for verification. Please update the subject chart.' (Site from CRA).	Emily Dougherty (b) (4)	19 Nov 2020 17:52:33
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	17 Nov 2020 20:33:30
	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '14 Nov 2020'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '89'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '98.5' F	Emily Carney (b) (4)	16 Nov 2020 15:50:06



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Severe (Severe)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:50:06



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 5 (Day 5)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:08
User entered '15 Nov 2020'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:11
User entered '0'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:13
User entered '92'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:17
User entered '99' F	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:19
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:21
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:29
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:30
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:37
User entered 'Severe (Severe)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:41
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:45
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:49
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:57
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:34:59
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:04
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:06
User entered 'Moderate (Moderate)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:10
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:15
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:17
User entered 'None (None)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:19
User entered 'Mild (Mild)'	Emily Carney (b) (4)	16 Nov 2020 15:51:19

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 6 (Day 6)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:37
User entered '16 Nov 2020'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:39
User entered '0'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:42
User entered '95'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:44
User entered '99.0' F	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:46
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:49
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:54
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:56
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:35:58
User entered 'Severe (Severe)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:00
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:02
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:05
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:42
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:44
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:50
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:51
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:54
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:36:56
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:07
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:16
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 17:19:48

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 7 (Day 7)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:23
User entered '17 Nov 2020'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:25
User entered '0'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:28
User entered '95'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	17 Nov 2020 19:43:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:31
User entered '100.5' F	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:33
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:35
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:38
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:40
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:48
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:52
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:54
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:37:57
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:01
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:06
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:08
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:10
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:11
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:13
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:16
User entered 'None (None)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:38:18
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	17 Nov 2020 19:43:29

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 8 (Day 8)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '18 Nov 2020'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '96'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	19 Nov 2020 17:55:53

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '99' F	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 10:58:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Un-verified.	Jennifer Nagg (b) (4)	24 Nov 2020 16:02:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	24 Nov 2020 16:02:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Severe (Severe)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	19 Nov 2020 17:55:53



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 9 (Day 9)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '19 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '95'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '99' F	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Severe (Severe)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:57:28

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 10 (Day 10)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '20 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '95'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '99' F	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 14:58:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 11 (Day 11)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '21 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '96'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	23 Nov 2020 15:11:47

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '99.1' F	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:11:47

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 12 (Day 12)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '22 Nov 2020'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '0'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '96'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	23 Nov 2020 15:12:59

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered '98.8' F	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Moderate (Moderate)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'None (None)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:15:45
User entered 'Mild (Mild)'	Emily Dougherty (b) (4)	23 Nov 2020 15:12:59



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 13 (Day 13)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:14:53
User entered '23 Nov 2020'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:14:54
User entered '0'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:01
User entered '96'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:09
User entered '98.9' F	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:10
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:13
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:15
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:20
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:22
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:28
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:32
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:41
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:43
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:45
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:53
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:55
User entered 'Moderate (Moderate)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:15:59
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:16:01
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:16:03
User entered 'None (None)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:16:06
User entered 'Mild (Mild)'	Jennifer Nagg (b) (4)	24 Nov 2020 14:10:32

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 14 (Day 14)'	Jamie Fries (b) (4)	25 Nov 2020 19:49:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '24 Nov 2020'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:49:24



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:49:24

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:49:24

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	25 Nov 2020 19:49:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.9' F	(b) (4) Jamie Fries (b) (4) (b) (4)	25 Nov 2020 19:49:24

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
	(b) (4)	
User entered empty.	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
	(b) (4)	
User entered empty.	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	



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Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:49:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
	(b) (4)	
User entered empty.	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:49:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:17:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4) Jamie Fries (b) (4)	25 Nov 2020 19:49:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
	(b) (4)	
User entered empty.	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	



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Form: Symptom Log (14)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:08
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:53:53
User entered empty.	(b) (4)	
	Jamie Fries (b) (4)	25 Nov 2020 19:49:24
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 15 (Day 15)'	Dominic Kramer (b) (4)	01 Dec 2020 13:53:52

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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:18:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '25 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '99.1' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52



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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:19:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52



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Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:20:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:53:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 16 (Day 16)'	Dominic Kramer (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '26 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '99.1' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13



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Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:22:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:23:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:24:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:24:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:25:49
DataPoint Un-verified.		04 Mar 2021 05:25:43
DataPoint Verified.		04 Mar 2021 05:25:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:25:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:25:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:25:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:26:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:26:20
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:56:13



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 17 (Day 17)'	Dominic Kramer (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:27:25
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '27 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:27:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:27:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 13:59:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:27:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.6' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:27:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:28:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:05
DataPoint Un-verified.		04 Mar 2021 05:52:00
DataPoint Verified.		04 Mar 2021 05:51:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:08
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:52:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:03
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:53:33
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 13:59:36

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 18 (Day 18)'	Dominic Kramer (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:01
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '28 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:17
DataPoint Un-verified.		04 Mar 2021 05:54:10
DataPoint Verified.		04 Mar 2021 05:54:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 14:06:43

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.3' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:54:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Moderate (Moderate)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:56:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:57:11
DataPoint Un-verified.		04 Mar 2021 05:57:05
DataPoint Verified.		04 Mar 2021 05:56:59
DataPoint Un-verified.		04 Mar 2021 05:56:56
DataPoint Verified.		04 Mar 2021 05:56:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:06:43

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 19 (Day 19)'	Dominic Kramer (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:31
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '29 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.4' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:43
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:58:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:10
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:16
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 05:59:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:08:26

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 20 (Day 20)'	Dominic Kramer (b) (4)	01 Dec 2020 14:11:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '30 Nov 2020'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:00:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	01 Dec 2020 14:11:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.1' F	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:33
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:01:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:39
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:02:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Dominic Kramer (b) (4) (b) (4)	01 Dec 2020 14:11:44



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 21 (Day 21)'	Emily Dougherty (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:03:20
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '01 Dec 2020'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:03:47
DataPoint Un-verified.		04 Mar 2021 06:03:44
DataPoint Verified.		04 Mar 2021 06:03:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:07
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '97'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:11
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.1' F	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:32
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:35
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12



US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:04:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:05:20
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:05:53
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:12
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12



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Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:27
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Mild (Mild)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:47
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:06:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Emily Dougherty (b) (4) (b) (4)	03 Dec 2020 18:39:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Day 22 (Day 22)'	Jennifer Nagg (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:07:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '2 Dec 2020'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:07:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '0'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:07:55
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '96'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
User entered '%'	System	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '98.1' F	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:30
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09



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Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:38
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:41
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:44
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:46
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:51
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:08:58
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:09:01
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:09:05
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:31:00

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:00
DataPoint Verified.		04 Mar 2021 06:09:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'None (None)'	(b) (4) Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:09

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:31:00

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:41:42
User entered '11 Nov 2020'	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:31:00

[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 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:41:58
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:31:00

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 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 04:34:37
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).		18 Nov 2020 04:34:26
DataPoint Verified.		17 Nov 2020 20:42:03
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 'doing that now' (Site from System).	Jennifer Nagg (b) (4)	13 Nov 2020 16:29:19
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	13 Nov 2020 16:29:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	13 Nov 2020 16:29:08
Query 'Data is required. Please complete.' answered with 'not resulted yet' (Site from System).	Jennifer Nagg (b) (4)	12 Nov 2020 00:37:04
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:20:14
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:07
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:36:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 00:36:55
User entered '11 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	12 Nov 2020 00:36:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:20:14
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14



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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:09
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:36:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 00:36:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	12 Nov 2020 00:36:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:20:14
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:14
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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[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 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:17
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 00:36:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 00:36:55
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	12 Nov 2020 00:36:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 20:20:14
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:20
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:42:23
User entered empty.	Lalicia Roman (b) (4)	11 Nov 2020 20:20:14

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Folder: Covid-19 Assessment 11 Nov 2020

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:09
User entered 'I'	System	13 Nov 2020 16:29:08

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Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 12 Aug 2021 13:31:00

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

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 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 04:59:32
User closed query 'Please reconcile as symptom log on 14Nov2020 notes O2 of 89% and ending on 15Nov2020' (Site from CRA).		20 Nov 2020 04:59:30
Query 'Please reconcile as symptom log on 14Nov2020 notes O2 of 89% and ending on 15Nov2020' answered with 'updated form' (Site from CRA).	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:09
DataPoint Un-verified.	Jennifer Nagg (b) (4)	19 Nov 2020 18:25:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Nov 2020 18:25:56
User opened query 'Please reconcile as symptom log on 14Nov2020 notes O2 of 89% and ending on 15Nov2020' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 03:37:24
DataPoint Verified.		17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 04:59:34
DataPoint Un-verified.	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
User entered '14 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 04:59:35
DataPoint Un-verified.	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
User entered '15 Nov 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 04:59:37
DataPoint Un-verified.	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
User entered '89' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	19 Nov 2020 18:26:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
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).		23 Feb 2021 03:51:41
Query 'Per CDM: It appears that both 'Did the subject Emily Carney (b) (4) 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).	(b) (4)	18 Feb 2021 18:56:58
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 05:33:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Generated On: 12 Aug 2021 13:31:00

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
DataPoint Verified.		15 Apr 2021 10:56:40
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User entered empty; reason for change Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'		
	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
DataPoint Verified.		15 Apr 2021 10:56:43
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User entered empty; reason for change Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 19:24:01



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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
DataPoint Verified.		15 Apr 2021 10:56:55
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User entered empty; reason for change Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

US3802185

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
DataPoint Verified.		15 Apr 2021 10:56:47
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Un-verified.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
Signature has been broken.	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User entered empty; reason for change Data Entry Error	(b) (4)	
	Emily Carney (b) (4)	18 Feb 2021 18:56:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[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 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered 'No (N)'	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01



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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:31:00

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:23
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 19:24:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:31:00

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:52:26
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:35
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Nov 2020 20:18:45

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 3 (Day 3)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

**US3802185**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered '13 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 5 (Day 5)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

**US3802185**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered '15 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 7 (Day 7)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:31:00

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered '17 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 9 (Day 9)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:31:00

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:44:54
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:34:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 14:34:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	24 Nov 2020 14:34:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:26:21
DataPoint Verified.		17 Nov 2020 21:02:08
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 19:52:15
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	24 Nov 2020 14:44:56
User entered '19 Nov 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4)	24 Nov 2020 14:34:10
DataPoint Un-verified.	(b) (4) (u) (4), (u) (6)	18 Nov 2020 13:26:22
DataPoint Verified.		17 Nov 2020 21:02:08
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 14 (Day 14)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:31:00

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:17:11
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:41:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 14:41:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Dougherty (b) (4)	24 Nov 2020 14:41:19
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:26:37
DataPoint Verified.		17 Nov 2020 21:02:08
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 19:52:15
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:17:12
User entered '24 Nov 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4)	24 Nov 2020 14:41:19
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:26:40
DataPoint Verified.		17 Nov 2020 21:02:08
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 21 (Day 21)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

US3802185

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:31:00

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
DataPoint Verified.		15 Feb 2021 16:01:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
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	08 Dec 2020 21:02:31
User entered 'Yes (Y)' reason for change: Data Entry Error	System	08 Dec 2020 21:02:31
DataPoint Un-verified.	Emily Dougherty (b) (4)	08 Dec 2020 21:02:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:26:48
		17 Nov 2020 21:02:08
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 19:52:15
User entered empty.	Jennifer Nagg (b) (4)	17 Nov 2020 19:52:15
	(b) (4)	

US3802185

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:31:00

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
DataPoint Verified.		15 Feb 2021 16:01:19
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Emily Dougherty (b) (4)	08 Dec 2020 21:02:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:26:54
DataPoint Verified.		17 Nov 2020 21:02:08
User entered empty.	Jennifer Nagg (b) (4)	17 Nov 2020 19:52:15
	(b) (4)	

**US3802185**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
User accepted default value 'Day 28 (Day 28)'	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

US3802185

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:31:00

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
DataPoint Verified.		15 Feb 2021 16:07:57
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
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	08 Dec 2020 21:02:06
User entered 'Yes (Y)' reason for change: Data Entry Error	System	08 Dec 2020 21:02:06
DataPoint Un-verified.	Emily Dougherty (b) (4)	08 Dec 2020 21:02:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:27:03
		17 Nov 2020 21:02:08
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 19:52:15
User entered empty.	Jennifer Nagg (b) (4)	17 Nov 2020 19:52:15
	(b) (4)	

US3802185

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:31:00

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:13
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:08:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per GCL Lab Recon: Saliva: Samples dated 08DEC2020 for Day 28 is reported under Illness visit 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) (b) (4), (b) (6)	11 Jan 2021 08:08:51
Query 'Per GCL Lab Recon: Saliva: Samples dated 08DEC2020 for Day 28 is reported under Illness visit in EDC, however same is reported for Unscheduled visit in PPD central lab. Please confirm the correct visit, Thank you.' answered with 'was collected for convalescent visit' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	10 Jan 2021 11:27:06
User opened query 'Per GCL Lab Recon: Saliva: Samples dated 08DEC2020 for Day 28 is reported under Illness visit 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), (b) (6)	16 Dec 2020 05:34:45
User entered '08 Dec 2020' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	08 Dec 2020 21:02:06
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 13:27:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:02:08
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	17 Nov 2020 19:52:15

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Query 'Please reconcile and add saliva log' canceled (Site from CRA).	(b) (4)	18 Nov 2020 13:24:55
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:54:52
User opened query 'Please reconcile and add saliva log' (Site from CRA).	(b) (4)	15 Nov 2020 23:09:24
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	11 Nov 2020 20:21:29
	(b) (4)	



**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:54
User entered '11 Nov 2020'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:21:29

US3802185

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[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 09:15:23
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:54:55
User entered 'Clinic (Clinic)'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:21:29

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:23
User entered 'SICKD1'	System	11 Nov 2020 20:21:29

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:55:24
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '11 Nov 2020'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '14:53'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User entered '11 Nov 2020 14:53'	System	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Query 'Per CDM: Per page 25 of CCGs version 2.0, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and reconcile, else clarify. Thank you. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:30:13
User opened query 'Per CDM: Per page 25 of CCGs version 2.0, "HEIGHT" and "WEIGHT" are to be captured on Illness Visit Day 1. Please review and reconcile, else clarify. Thank you. ' (Site from DM).		19 Nov 2020 13:53:16
DataPoint Verified.		17 Nov 2020 20:55:24
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 20:23:53
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 20:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:23:53
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 20:22:12
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12
DataPoint set to visible.	System	11 Nov 2020 20:21:29



US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 20:23:53
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 20:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:23:53
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Nov 2020 20:22:12
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12
DataPoint set to visible.	System	11 Nov 2020 20:21:29

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '36' C	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered 'Other (Other)'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered 'infrared'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '95'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User entered 'bpm'	System	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '20'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User entered 'breaths/min'	System	11 Nov 2020 20:22:12



US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '126'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User entered 'mmHg'	System	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:55:24
User entered '83'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:12

**US3802185**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29
User entered 'mmHg'	System	11 Nov 2020 20:22:12

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29

US3802185

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:29

US3802185

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:55:56
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:31

US3802185

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	17 Nov 2020 20:55:56
User entered '11 Nov 2020'	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:31



US3802185

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:31:00

[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 09:15:40
DataPoint Verified.	(b) (4)	15 Apr 2021 10:56:01
User signature succeeded.	Judith Martin (b) (4)	31 Mar 2021 19:49:49
DataPoint Un-verified.	(b) (4)	
	Emily Dougherty (b) (4)	30 Mar 2021 18:09:00
Signature has been broken.	(b) (4)	
	Emily Dougherty (b) (4)	30 Mar 2021 18:09:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Emily Dougherty (b) (4)	30 Mar 2021 18:09:00
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 17:19:07
User closed query 'Per ETRTR: Lab results for Coronavirus SARS-CoV-2 are present in PPDPreclarus central lab. Please update or clarify.' (Site from CRA).	(b) (4)	17 Feb 2021 17:19:05
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
	(b) (4)	
Query 'Per ETRTR: Lab results for Coronavirus SARS-CoV-2 are present in PPDPreclarus central lab. Please update or clarify.' answered with 'Updated' (Site from CRA).	Jennifer Nagg (b) (4)	09 Feb 2021 16:45:36
DataPoint Un-verified.	(b) (4)	
	Jennifer Nagg (b) (4)	09 Feb 2021 16:45:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Nagg (b) (4)	09 Feb 2021 16:45:29
User opened query 'Per ETRTR: Lab results for Coronavirus SARS-CoV-2 are present in PPDPreclarus central lab. Please update or clarify.' (Site from CRA).	(b) (4), (b) (6)	26 Nov 2020 20:49:14
DataPoint Verified.	(b) (4)	17 Nov 2020 20:56:32
User entered 'No (N)'	Lalicia Roman (b) (4)	11 Nov 2020 20:22:38
	(b) (4)	

US3802185

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:31:00

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:15:40
User closed query 'Per Lab Recon: SARS-COV2:Please kindly update the missing sample date of collection.Thank you.' (Site from DM).		17 Apr 2021 18:29:07
Query 'Per Lab Recon: SARS-COV2:Please kindly update the missing sample date of collection.Thank you.' answered with 'updated - illness visit was in combination to visit 3. Blood was taken using visit 3 kit ' (Site from DM).	Emily Dougherty (b) (4) (b) (4)	30 Mar 2021 18:10:56
User opened query 'Per Lab Recon: SARS-COV2:Please kindly update the missing sample date of collection.Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 23:27:23
User signature succeeded.	Judith Martin (b) (4) (b) (4)	13 Feb 2021 12:35:25
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 20:56:32
User entered empty.	Lalicia Roman (b) (4) (b) (4)	11 Nov 2020 20:22:38

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	08 Dec 2020 21:00:22
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '08 Dec 2020'	Emily Dougherty (b) (4)	08 Dec 2020 21:00:22
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:13
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Clinic (Clinic)'	Emily Dougherty (b) (4)	08 Dec 2020 21:00:22
	(b) (4)	

**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	08 Dec 2020 21:00:22

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:34
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:36
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '08 Dec 2020'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	



US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:37
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '08:30'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Dec 2020 08:30'	System	08 Dec 2020 21:01:28

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:40
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered missing code ND - Not Done.	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	
DataPoint set to visible.	System	08 Dec 2020 21:00:22

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered missing code ND - Not Done.	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	
DataPoint set to visible.	System	08 Dec 2020 21:00:22

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:48
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '98.4' F	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:50
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Other (Other)'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:52
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Infrared'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:54
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '88'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	



**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Dec 2020 21:01:28

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:56
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '16'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Dec 2020 21:01:28

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:03:59
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '136'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Dec 2020 21:01:28

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:04:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '80'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:28
	(b) (4)	

**US3802185**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Dec 2020 21:01:28

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:04:17
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'No (N)'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:38
	(b) (4)	



US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:04:18
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered empty.	Emily Dougherty (b) (4)	08 Dec 2020 21:01:38
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:31:00

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:04:33
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 08 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). User signature succeeded.	(b) (4), (b) (6)	15 Feb 2021 07:38:59
	Judith Martin (b) (4)	13 Feb 2021 12:35:25
	(b) (4)	
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 08 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 'site did not have convalescent blood kits so used unscheduled visit kit. the purpose of this visit was convalescent.' (Site from DM).	Jennifer Nagg (b) (4)	12 Feb 2021 16:30:51
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 08 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 07:24:11
User entered 'Yes (Y)'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:46
	(b) (4)	

US3802185

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:31:00

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 16:04:40
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
	(b) (4)	
User entered '08 Dec 2020'	Emily Dougherty (b) (4)	08 Dec 2020 21:01:46
	(b) (4)	

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:09:30

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:09:30

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:31:00

[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 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Clinic (Clinic)'	Dominic Kramer (b) (4)	08 Jan 2021 15:09:30

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 15:09:30

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:10:01



**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:31:00**

[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 20:41:45
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:41:43
User entered '0'	(b) (4) Emily Dougherty (b) (4)	08 Apr 2021 17:45:27
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:56:56

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
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 01:56:28
User signature succeeded.	Judith Martin (b) (4)	08 Apr 2021 18:41:43
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 blank field' (Site from DM).	(b) (4) Emily Dougherty (b) (4)	08 Apr 2021 17:45:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	Emily Dougherty (b) (4)	08 Apr 2021 17:45:27
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 11:09:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:56:56

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Placebo (Placebo)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:30:28
User entered 'Placebo (Placebo)'	Dominic Kramer (b) (4)	08 Jan 2021 15:10:01
	(b) (4)	

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:30:28
User entered 'Placebo (Placebo)'	Dominic Kramer (b) (4)	08 Jan 2021 15:10:01
	(b) (4)	

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:31:00

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:10:01



**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:31:00**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '1'	System	08 Jan 2021 15:10:01

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'I'	System	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '163.5' cm	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '180' lb	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '30.60655'	System	08 Jan 2021 15:13:32
DataPoint set to visible.	System	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '163.5' cm	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '180' lb	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '30.60655'	System	08 Jan 2021 15:13:32
DataPoint set to visible.	System	08 Jan 2021 15:10:01



US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User accepted default value 'Pre-Dose (PREDOSE)'	Dominic Kramer (b) (4) (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '08:41'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '8 Jan 2021 08:41'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '97.4' F	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Other (Other)'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Infrared'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32



US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '58'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'bpm'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'breaths/min'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '124'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'mmHg'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '76'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'mmHg'	System	08 Jan 2021 15:13:32



US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '163.5' cm	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '180' lb	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:31:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '30.60655'	System	08 Jan 2021 15:13:32
DataPoint set to visible.	System	08 Jan 2021 15:10:01

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User accepted default value 'Post-Dose (POSTDOSE)'	Dominic Kramer (b) (4) (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '09:46'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '8 Jan 2021 09:46'	System	08 Jan 2021 15:13:32



US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '97.1' F	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Other (Other)'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Infrared'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '90'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'bpm'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '12'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'breaths/min'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '109'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32



**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'mmHg'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '71'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'mmHg'	System	08 Jan 2021 15:13:32

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:13:41

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:31:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:13:41

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Urine (URINE)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Negative (NEGATIVE)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'No (N)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	Dominic Kramer (b) (4)	08 Jan 2021 15:14:00

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered empty.	System	08 Jan 2021 15:14:00

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22

US3802185

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

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 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered empty.	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'mRNA-1273'	System	08 Jan 2021 15:14:22
DataPoint set to visible.	System	08 Jan 2021 15:10:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '09:18'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '8 Jan 2021 09:18'	System	08 Jan 2021 15:14:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Left Arm (LEFT ARM)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'ONCE'	System	08 Jan 2021 15:14:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 15:14:22

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:43



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:14:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '09:10'	(b) (4) Dominic Kramer (b) (4)	08 Jan 2021 15:14:43

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '8 Jan 2021 09:10'	System	08 Jan 2021 15:14:43

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	08 Jan 2021 15:15:16

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '8 Jan 2021'	Dominic Kramer (b) (4)	08 Jan 2021 15:15:16

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:31:00**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '09:13'	Dominic Kramer (b) (4)	08 Jan 2021 15:15:16

**US3802185**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:31:00**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered '8 Jan 2021 09:13'	System	08 Jan 2021 15:15:16

US3802185

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'Yes (Y)'	Dominic Kramer (b) (4)	08 Jan 2021 15:15:24



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:45
User entered 'I'	System	08 Jan 2021 15:15:24

**US3802185**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	15 Jan 2021 19:03:40
	(b) (4)	

US3802185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '15 Jan 2021'	Lalicia Roman (b) (4)	15 Jan 2021 19:03:40
	(b) (4)	

US3802185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Lalicia Roman (b) (4)	15 Jan 2021 19:03:40
	(b) (4)	

US3802185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered empty.	Lalicia Roman (b) (4)	15 Jan 2021 19:03:40
	(b) (4)	

US3802185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered 'Yes (Y)'	Lalicia Roman (b) (4)	15 Jan 2021 19:03:44
	(b) (4)	

**US3802185**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User entered 'I'	System	15 Jan 2021 19:03:44

**US3802185**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:24:15
User entered 'I'	System	15 Jan 2021 19:03:44
DataPoint set to visible.	System	15 Jan 2021 19:03:44



**US3802185**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:56:15

**US3802185**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '5 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:56:15

**US3802185**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[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 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:56:15

**US3802185**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'OLD29'	System	05 Feb 2021 13:56:15

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User accepted default value 'Pre-Dose (PREDOSE)'	Lalicia Roman (b) (4) (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '5 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '08:45'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40



**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered '5 Feb 2021 08:45'	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '97.2' F	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '89'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'bpm'	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '16'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'breaths/min'	System	05 Feb 2021 13:57:40



US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '122'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'mmHg'	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '71'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'mmHg'	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User accepted default value 'Post-Dose (POSTDOSE)'	Lalicia Roman (b) (4) (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '5 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 14:50:46
User entered '09:46' reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 13:57:40
User entered empty.	System	05 Feb 2021 13:57:40
	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	



**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered '5 Feb 2021 09:46'	System	05 Feb 2021 14:50:46
User entered empty.	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).		16 Feb 2021 06:41:18
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
	(b) (4)	
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'ncs' (Site from DM).	Melissa Andrasko (b) (4)	12 Feb 2021 18:49:41
	(b) (4)	
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:36:44
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)	08 Feb 2021 15:36:31
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 'recorded on infrared thermometer' (Site from System).	Lalicia Roman (b) (4)	05 Feb 2021 14:51:08
	(b) (4)	
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	05 Feb 2021 14:50:46
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Feb 2021 14:50:46
User entered '96.7' F reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 13:57:40
User entered empty.	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 14:50:46
User entered '88' reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 13:57:40
User entered empty.	System	05 Feb 2021 13:57:40
	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'bpm'	System	05 Feb 2021 14:50:46
User entered empty.	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 14:50:46
User entered '16' reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 13:57:40
User entered empty.	System	05 Feb 2021 13:57:40
	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'breaths/min'	System	05 Feb 2021 14:50:46
User entered empty.	System	05 Feb 2021 13:57:40



US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 14:50:46
User entered '133' reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 13:57:40
User entered empty.	System	05 Feb 2021 13:57:40
	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'mmHg'	System	05 Feb 2021 14:50:46
User entered empty.	System	05 Feb 2021 13:57:40

US3802185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:31:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 14:50:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 14:50:46
User entered '77' reason for change: Data Entry Error	Lalicia Roman (b) (4)	05 Feb 2021 14:50:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 13:57:40
User entered empty.	System	05 Feb 2021 13:57:40
	Lalicia Roman (b) (4)	05 Feb 2021 13:57:40
	(b) (4)	

**US3802185**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'mmHg'	System	05 Feb 2021 14:50:46
User entered empty.	System	05 Feb 2021 13:57:40

**US3802185**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:48

**US3802185**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:48

US3802185

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:31:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '5 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37



**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Urine (URINE)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Negative (NEGATIVE)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered empty.	System	05 Feb 2021 14:16:37

**US3802185**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30

US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30



US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

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 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30

**US3802185**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'mRNA-1273'	System	05 Feb 2021 14:17:30
DataPoint set to visible.	System	15 Jan 2021 19:03:44

US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '5 Feb 2021'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30

US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '09:14'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30

**US3802185**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered '5 Feb 2021 09:14'	System	05 Feb 2021 14:17:30

US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 14:17:30

US3802185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:31:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'ONCE'	System	05 Feb 2021 14:17:30

**US3802185**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:31:00**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 14:17:30



US3802185

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:31:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	05 Feb 2021 13:57:59

**US3802185**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:08
User entered 'I'	System	05 Feb 2021 13:57:59

**US3802185**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:15

US3802185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:31:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Feb 2021 16:23:35
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Feb 2021 16:23:35
Signature has been broken.	Emily Carney (b) (4)	18 Feb 2021 16:23:35
User entered '12 Feb 2021' reason for change: Data Entry Error	Emily Carney (b) (4)	18 Feb 2021 16:23:35
Amendment Manager: User opened query 'OL Safety System Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:24:42
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered '9 Feb 2021'	Emily Carney (b) (4)	09 Feb 2021 14:42:15

**US3802185**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Contact Made (CONTACT MADE)'	Emily Carney (b) (4)	09 Feb 2021 14:42:15

**US3802185**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:31:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered empty.	Emily Carney (b) (4)	09 Feb 2021 14:42:15

**US3802185**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User signature succeeded.	Judith Martin (b) (4)	13 Feb 2021 12:35:25
User entered 'Yes (Y)'	(b) (4) Emily Carney (b) (4) (b) (4)	09 Feb 2021 14:42:19

**US3802185**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:31:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:03:04
User entered 'I'	System	09 Feb 2021 14:42:19



**US3802185**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:47:27

**US3802185**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '11 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:47:27

**US3802185**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[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 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Clinic (Clinic)'	(b) (4) Lalicia Roman (b) (4) (b) (4)	11 Mar 2021 15:47:27

**US3802185**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:31:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered 'OLD57'	System	11 Mar 2021 15:47:27

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

US3802185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '11 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '08:41'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered '11 Mar 2021 08:41'	System	11 Mar 2021 15:50:21



US3802185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:31:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '99.6' F	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Other (Other)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'infrared'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '83'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered 'bpm'	System	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '18'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered 'breaths/min'	System	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '103'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21



**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered 'mmHg'	System	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '71'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered 'mmHg'	System	11 Mar 2021 15:50:21

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03

**US3802185**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:31:00**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03

**US3802185**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'No (N)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:26

**US3802185**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:31:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered empty.	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:50:26

US3802185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:58:57



US3802185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:31:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '11 Mar 2021'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:58:57

**US3802185**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User signature succeeded.	Judith Martin (b) (4)	12 Mar 2021 14:53:11
User entered '08:45'	(b) (4) Lalicia Roman (b) (4)	11 Mar 2021 15:58:57

**US3802185**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:31:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:59:03
User entered '11 Mar 2021 08:45'	System	11 Mar 2021 15:58:57

US3802185

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:31:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:11:29
User closed query 'The entry is "No" however Adverse Event log is completed. Please verify and update this Entry to Yes.' (Site from CRA).		24 Nov 2020 14:11:28
Query 'The entry is "No" however Adverse Event log is completed. Please verify and update this Entry to Yes.' answered with 'updated' (Site from CRA).	Jennifer Nagg (b) (4)	24 Nov 2020 14:00:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 14:00:20
User opened query 'The entry is "No" however Adverse Event log is completed. Please verify and update this Entry to Yes.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 14:06:25
DataPoint Un-verified.		18 Nov 2020 13:59:34
DataPoint Verified.		18 Nov 2020 13:59:23
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	12 Nov 2020 00:41:57
User entered 'Yes (Y)'	(b) (4) Lalicia Roman (b) (4)	12 Oct 2020 20:27:17
	(b) (4)	

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:20:10
DataPoint Un-verified.		18 Nov 2020 13:24:05
DataPoint Verified.		18 Nov 2020 13:23:56
Reviewed for Safety.		16 Nov 2020 17:29:13
User entered 'USA-US098-2020-mRNA-1273-P301000004'		16 Nov 2020 17:29:08
User entered 'New'		16 Nov 2020 17:29:08

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:51:08
		23 Nov 2020 16:19:11
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)	23 Nov 2020 15:19:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:19:08
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 to symptomatic covid-19' (Site from DM).	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 15:18:59
Data point term sent to Coder DataPoint Un-verified.	System Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 15:18:08 23 Nov 2020 15:17:46
Coding entries removed.	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 15:17:46
User entered 'Symptomatic COVID 19' reason for change: Data Entry Error	Emily Dougherty (b) (4) (b) (4)	23 Nov 2020 15:17:46
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). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:21:32
		18 Nov 2020 13:23:09
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)	13 Nov 2020 16:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 16:32:47
Data point term sent to Coder	System	13 Nov 2020 16:32:26

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID 19'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:10
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38



**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:12
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:14
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:16
User entered '11 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:18
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:00
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
DataPoint Un-verified.	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:23:23
User entered 'Yes (Y)'	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:02
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
DataPoint Un-verified.	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:47
	(b) (4)	
User entered '2 Dec 2020' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:47
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 21:48:49
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'continues' (Site from Safety).	Jennifer Nagg (b) (4)	24 Nov 2020 14:01:02
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:40:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:38
	(b) (4)	

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:25
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38



**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 16:31:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:30
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:33
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:35
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:37
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:38
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38



**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered 'Not Related (NOT RELATED)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38



US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:11
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
Signature has been broken.	Jennifer Nagg (b) (4)	15 Feb 2021 20:33:06
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'Per CDM: Other action taken=none, however, according to the Narrative, subject is taking TYLENOL for Headaches, which is also listed on the ConMed eCRF. Please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 11:56:53
Query 'Per CDM: Other action taken=none, however, according to the Narrative, subject is taking TYLENOL for Headaches, which is also listed on the ConMed eCRF. Please confirm and update where necessary. Thank you.' answered with 'updated' (Site from DM).	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:53
DataPoint Un-verified.	Jennifer Nagg (b) (4)	03 Dec 2020 18:46:38
User entered '0' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	03 Dec 2020 18:46:38
User opened query 'Per CDM: Other action taken=none, however, according to the Narrative, subject is taking TYLENOL for Headaches, which is also listed on the ConMed eCRF. Please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:31:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '1'	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:14
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE indication. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).		18 Feb 2021 11:49:02
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE indication. Please review and add a Con Medication as appropriate or update action taken' answered with 'con meds are recorded during this time frame for treatment of symptoms associated with covid' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	15 Feb 2021 20:31:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE indication. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:07:08
User signature succeeded.	Judith Martin (b) (4) (b) (4)	01 Feb 2021 16:29:47
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:38
User entered '1' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:46:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:22
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
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)	
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 'updated' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 18:04:07
DataPoint Un-verified.	Jennifer Nagg (b) (4)	03 Dec 2020 18:48:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Jennifer Nagg (b) (4)	03 Dec 2020 18:47:47
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).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:49
User closed query 'Data is required. Please complete.' (Site from System).		18 Nov 2020 13:23:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 16:31:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	13 Nov 2020 16:31:48
User opened query 'Data is required. Please complete.' (Site from System).	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:48
User entered empty.	System	13 Nov 2020 16:31:38
	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	13 Nov 2020 16:31:38

US3802185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:31:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:13:29
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
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)	01 Dec 2020 21:48:56
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 'added' (Site from Safety).	Jennifer Nagg (b) (4)	24 Nov 2020 16:15:46
DataPoint Un-verified.	Jennifer Nagg (b) (4)	24 Nov 2020 16:15:32
User entered 'subject using albuterol inhaler and taking tylenol for headaches. Started aspirin to prevent DVTs.' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	24 Nov 2020 16:15:32
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)	20 Nov 2020 15:41:09
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:23:56
User entered empty.	Jennifer Nagg (b) (4)	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 16:31:38

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 16:31:38



**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:42
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Haemoptysis, LLT: Sputum bloody - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:16:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:16:53
Data point term sent to Coder	System	24 Nov 2020 16:15:16
User entered 'Bloody sputum'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (v) (4), (b) (6)	24 Nov 2020 16:36:44
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:45
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 06:14:03
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User closed query 'PV Query: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:04:34
Query 'PV Query: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' answered with 'updated' (Site from Safety).	Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:48:50
DataPoint Un-verified.	Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:48:40
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	03 Dec 2020 18:48:40
User opened query 'PV Query: As an event of Covid-19 has already been reported, and this is only a symptom of Covid-19 and not the actual infection, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:13:51
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' canceled (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:13:33
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:13:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:36:47
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:49
User entered '20 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:36:51
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User entered empty.	System	24 Nov 2020 16:13:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:53
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:54
User entered '20 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:56
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User entered empty.	System	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:36:59
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:02
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:05
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59



US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:07
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:09
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:10
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:13
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:14
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:16
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:18
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

US3802185

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:20
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:37:21
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 16:14:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:13:59
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:45
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 16:14:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:13:59
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:47
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:14:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 16:14:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 16:13:59
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:48
User entered 'l'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:50
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:51
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:31:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:54
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59



**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:44:59
User entered 'small bloody streak in sputum with morning cough'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User entered '0'	System	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42
User entered '0'	System	24 Nov 2020 16:13:59

**US3802185**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:20:42

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:31:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:29:10
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:47:33

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
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.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:31:42
Data point term sent to Coder	System	09 Sep 2020 16:48:22
User entered 'Albuterol Inhaler'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Allergy Related Asthma'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'I'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'puff (PUFF)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'as needed (PRN)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2020). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).		18 Nov 2020 13:45:50
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2020). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Updated and confirmed to match Mh. ' (Site from DM).	Emily Carney (b) (4) (b) (4)	12 Nov 2020 20:16:12
User entered 'UN UNK 2020' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	12 Nov 2020 20:15:59
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2020). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:44:23
User entered 'UN UNK 2019'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		18 Nov 2020 13:45:52
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated ' (Site from DM).	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:38:10
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:38:05
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:44:42
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:12

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:48:12

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:48:12

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 16:48:12

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:49:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 16:49:44
Data point term sent to Coder	System	09 Sep 2020 16:49:24
User entered 'Atorvastatin'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'High Cholesterol'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '10'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).		18 Nov 2020 13:45:57
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:31
' answered with 'Updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:25
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:45:25
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 16:48:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:48:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 16:48:49



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 16:48:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:57:39
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.	Coder Import (b) (4)	09 Sep 2020 17:29:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 17:29:45
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 17:29:05
User entered 'Hydrochlorothiazide'	Dominic Kramer (b) (4)	09 Sep 2020 17:28:31
	(b) (4)	

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:04:35
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Patient did not include this information in original history with physician. It was listed at a visit at a later date. Medication start date listed in Con Med list.' (Site from DM).	Lisa Vavro (b) (4)	18 Feb 2021 16:10:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:40:37
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:29:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:57:39
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Participant did not report an underlying condition. This is what they reported. ' (Site from DM).	Emily Carney (b) (4)	12 Nov 2020 20:21:08

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). User entered 'Fluid retention'	(b) (4), (b) (6)  Dominic Kramer (b) (4) (b) (4)	10 Nov 2020 02:47:32  09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '25'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (6) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:31:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		18 Nov 2020 13:46:19
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:47
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:40
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:48:40
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:28:31

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:28:31

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:28:31

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:28:31

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:30:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:30:47
Data point term sent to Coder	System	09 Sep 2020 17:30:07
User entered 'Claritin'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Seasonal Allergies'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '10'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'as needed (PRN)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	8 Nov 2020 13:57:39
User entered 'UN UNK 1975'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).		18 Nov 2020 13:46:25
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:56
' answered with 'Updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:46:51
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:46:55
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:29:14

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:29:14

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:29:14

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:29:14

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:04:32
User closed query 'Please correct the name to Norethindrone' (Site from CRA).		24 Nov 2020 14:04:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: NORETHINDRONE [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:37:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 13:36:52
Query 'Please correct the name to Norethindrone' answered with 'updated' (Site from CRA).	Jennifer Nagg (b) (4)	24 Nov 2020 13:36:00
Coding entries removed.	(b) (4)	
	Jennifer Nagg (b) (4)	24 Nov 2020 13:35:53
	(b) (4)	
User entered 'Norethindrone' reason for change: Data Entry Error	Jennifer Nagg (b) (4)	24 Nov 2020 13:35:53
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:58:28
DataPoint Verified.		18 Nov 2020 13:57:39
		18 Nov 2020 13:51:04
User opened query 'Please correct the name to Norethindrone' (Site from CRA).		
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: NORETHINDRONE [NORETHISTERONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:23:40
	(b) (4)	

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:23:40
Data point term sent to Coder	System	09 Sep 2020 17:30:14
User entered 'Northinedrone'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Birth Control'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '.35'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (6) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4)	09 Sep 2020 17:30:07

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:30:07

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:30:07

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:30:07



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:30:07

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS, PRODUCT: KRILL OIL, PRODUCTSYNONYM: OMEGA 3 KRILL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 11:28:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 11:28:42
Data point term sent to Coder	System	09 Sep 2020 17:31:17
User entered 'Omega 3 Krill Oil'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'High Cholesterol'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '500'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).		18 Nov 2020 13:46:33
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:09
' answered with 'Updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:03
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:49:35
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:31:02



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:31:02

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:31:02

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:31:02

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM W/VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 07:05:41
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 Sep 2020 07:05:41
Data point term sent to Coder	System	09 Sep 2020 17:34:30
User entered 'Calcium W/ D3'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		18 Nov 2020 13:46:37
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'Updated' (Site from DM).	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:16
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:46:01
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Supplement'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
	(b) (4)	
DataPoint Un-verified.	Dominic Kramer (b) (4)	19 Jan 2021 18:50:35
	(b) (4)	
User entered '630/500' reason for change: Data Entry Error	Dominic Kramer (b) (4)	19 Jan 2021 18:50:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '1'	Dominic Kramer (b) (4)	09 Sep 2020 17:34:04
	(b) (4)	

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Other (OTHER)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
User closed query 'Per DM CLR: Please update this field to remove the extraneous data (numeric values = 630/500) as this should be recorded in Dose Administration field. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 09:14:56
Query 'Per DM CLR: Please update this field to remove the extraneous data (numeric values = 630/500) as this should be recorded in Dose Administration field. Please update accordingly. ' answered with 'extraneous data removed' (Site from DM).	Dominic Kramer (b) (4) (b) (4)	19 Jan 2021 18:51:00
DataPoint Un-verified.	Dominic Kramer (b) (4) (b) (4)	19 Jan 2021 18:50:35
User entered 'MG/IU' reason for change: Data Entry Error	Dominic Kramer (b) (4) (b) (4)	19 Jan 2021 18:50:35
User opened query 'Per DM CLR: Please update this field to remove the extraneous data (numeric values 630/500) as this should be recorded in Dose Administration field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:41:44
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '630mg Calcium 500IU D3'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:34:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:34:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:34:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:37:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:37:48
Data point term sent to Coder	System	09 Sep 2020 17:35:32
User entered 'Omeprazole'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'GERD'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '20'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).		18 Nov 2020 13:46:43
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'Updated ' (Site from DM).	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:30
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:25
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:50:30
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:34:43

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:34:43

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:34:43

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:34:43

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 17:38:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 17:38:43
Data point term sent to Coder	System	09 Sep 2020 17:37:38
User entered 'Singulair'	Dominic Kramer (b) (4)	09 Sep 2020 17:35:47
	(b) (4)	



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Seasonal Allergies'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '10'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'as needed (PRN)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2010'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:31:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).		18 Nov 2020 13:46:47
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:41
' answered with 'Updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Emily Carney (b) (4) (b) (4)	11 Nov 2020 18:47:37
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:17:23
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:35:47

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:35:47

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:35:47



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:35:47

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
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.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:38:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:38:42
Data point term sent to Coder	System	09 Sep 2020 17:37:39
User entered 'Vitamin D3'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:23:24
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Supplement'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '1000'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'IU (IU)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN UNK 2015'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:36:35



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:36:35

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:36:35

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:36:35

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:39:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 17:39:45
Data point term sent to Coder	System	09 Sep 2020 17:38:45
User entered 'Vitamin C'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		10 Nov 2020 03:18:47
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'Updated' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:22:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Nagg (b) (4) (b) (4)	04 Nov 2020 01:22:51
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 01:02:36
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Supplement'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '500'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'mg (mg)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'once daily (QD)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'UN Mar 2020'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Yes (Y)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Dominic Kramer (b) (4) (b) (4)	09 Sep 2020 17:38:28

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:38:28

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:38:28

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 17:38:28

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:48:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 23:48:26
Data point term sent to Coder	System	12 Oct 2020 20:32:06
User entered 'Keflex'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'post opp surgery'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '500'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:31:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 20:31:55
User entered 'mg (mg)' reason for change: Data Entry Error	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:55
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:31:49
User entered empty.	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'four times daily (QID)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'Oral (ORAL)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered empty.	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '7 Oct 2020'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '0'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered '10 Oct 2020'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:31:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:57:39
User entered 'No (N)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:31:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User entered '4'	System	12 Oct 2020 20:31:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User entered '1'	System	12 Oct 2020 20:31:49

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:48:57
User entered '804 (804)'	System	12 Oct 2020 20:31:49

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 14:17:55
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)	24 Nov 2020 13:57:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:57:12
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 13:38:54
User entered 'aspirin'	Jennifer Nagg (b) (4)	24 Nov 2020 13:38:25
	(b) (4)	



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:19:01
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:17:57
User entered 'dvt prevention'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:17:59
User entered '81'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:00
User entered 'mg (mg)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:02
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:03
User entered 'once daily (QD)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:05
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:08
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25



US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:09
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:12
User entered '17 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:14
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:16
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:17
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:18:20
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 13:38:25

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:38:25

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:38:25



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 13:38:25

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:19
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)	24 Nov 2020 16:02:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:02:53
Data point term sent to Coder	System	24 Nov 2020 16:01:36
User entered 'tylenol'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:37
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
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)	18 Feb 2021 13:15:41
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 'symptom of covid' (Site from DM).	Jennifer Nagg (b) (4) (b) (4)	15 Feb 2021 20:30:39
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)	26 Jan 2021 12:20:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 16:30:40
User entered 'headache'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:38
User entered '500'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:42
User entered 'mg (mg)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:43
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:47
User entered 'as needed (PRN)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04



US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:45
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:49
User entered 'Oral (ORAL)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:51
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:53
User entered '14 Nov 2020'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:54
User entered '0'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:30:56
User entered 'Yes (Y)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:31:00
User entered empty.	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:31:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	19 Feb 2021 14:47:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:31:01
User entered 'No (N)'	Jennifer Nagg (b) (4) (b) (4)	24 Nov 2020 16:01:04



**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 16:01:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 16:01:04

**US3802185**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:31:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 16:01:04

US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:31:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:57:49
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:58:42
User entered 'Yes (Y)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:30:08

US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:00

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:59:00
User entered '7 Oct 2020'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:30:46

US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:59:00
User entered 'liposuction'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:30:46

US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:59:00
User entered 'Other (OTHER)'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:30:46

US3802185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:31:00

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 13:59:00
User entered 'elective'	Lalicia Roman (b) (4) (b) (4)	12 Oct 2020 20:30:46



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:10
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'USA-US098-2020-MRNA-1273-P301000004'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:12
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:13
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:15
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:16
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:18
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:19
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:25
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08



US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:36
DataPoint Un-verified.		23 Nov 2020 21:33:22
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'Judith'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:35
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Martin'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered '3420 Fifth Ave'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Pittsburgh'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'PA'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered '15213'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
User entered 'US'	System	16 Nov 2020 17:29:36

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '3'	System	04 Dec 2020 16:22:01
User entered '2'	System	01 Dec 2020 21:45:45
User entered '1'	System	16 Nov 2020 17:29:36



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:10
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'USA-US098-2020-MRNA-1273-P301000004'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:13
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:15
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:16
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:19
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Judith'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 21:33:35
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Martin'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered '3420 Fifth Ave'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Pittsburgh'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'PA'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered '15213'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
User entered 'US'	System	16 Nov 2020 17:29:36

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '3'	System	04 Dec 2020 16:22:01
User entered '2'	System	01 Dec 2020 21:45:45
User entered '1'	System	16 Nov 2020 17:29:36



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
User entered '16/Nov/2020 12:29'	System	16 Nov 2020 17:29:36

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:31:00

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:31
DataPoint Verified.		23 Nov 2020 21:31:29
User entered 'I'		16 Nov 2020 17:29:36

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:10
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered	System	16 Nov 2020 17:29:08
'USA-US098-2020-MRNA-1273-P301000004'		

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:13
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:15
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:16
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:18
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:19
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:25
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:36
DataPoint Un-verified.		23 Nov 2020 21:33:22
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'Judith'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:35
DataPoint Un-verified.		23 Nov 2020 21:33:28
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'Martin'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered '3420 Fifth Ave'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Pittsburgh'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'PA'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered '15213'	System	16 Nov 2020 17:29:08



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:31
DataPoint Verified.		23 Nov 2020 21:31:29
User entered 'US'	System	16 Nov 2020 17:29:36

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '3'	System	04 Dec 2020 16:22:01
User entered '2'	System	01 Dec 2020 21:45:45
User entered '1'	System	16 Nov 2020 17:29:36

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 10:54:01
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '01/Dec/2020 21:45'	System	01 Dec 2020 21:45:45

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:31:00

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 10:54:04
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:21:50
User entered 'I'		01 Dec 2020 21:45:45

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:10
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'USA-US098-2020-MRNA-1273-P301000004'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:12
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:13
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:15
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:16
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:18
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:19
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:12
DataPoint Un-verified.		23 Nov 2020 21:33:25
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'No (N)'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:36
DataPoint Un-verified.		23 Nov 2020 21:33:22
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'Judith'	System	16 Nov 2020 17:29:08

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:33:35
DataPoint Un-verified.		23 Nov 2020 21:33:28
DataPoint Verified.		23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered 'Martin'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.		16 Nov 2020 17:29:29
User entered '3420 Fifth Ave'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'Pittsburgh'	System	16 Nov 2020 17:29:08



**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered 'PA'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:31:29
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:29:29
User entered '15213'	System	16 Nov 2020 17:29:08

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:31:00**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 21:45:31
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:31:29
User entered 'US'	System	16 Nov 2020 17:29:36

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 12 Aug 2021 13:31:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
	(b) (4)	
User entered '3'	System	04 Dec 2020 16:22:01
User entered '2'	System	01 Dec 2020 21:45:45
User entered '1'	System	16 Nov 2020 17:29:36

**US3802185**

**Folder: SAE USA-US098-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 12 Aug 2021 13:31:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 10:54:21
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered '04/Dec/2020 16:21'	(b) (4) System	04 Dec 2020 16:22:01

US3802185

Folder: SAE USA-US098-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:31:00

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 10:54:24
User signature succeeded.	Judith Martin (b) (4)	01 Feb 2021 16:29:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:22:01