

US3222462 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:02

All time stamps listed in this document are displayed in GMT

US3222462

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:39:13

Generated On: 09 Jun 2021 16:05:02

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[Participant ID](#)

US3222462

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

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US3222462

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Date of Informed Consent ( <i>dd MMM yyyy</i> )	2 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) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

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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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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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) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	01 AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	ALLERGIES, BACTRIM
Start date (dd MMM yyyy)	01 AUG 2014
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)	AUG 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	CHOLESCYCTECTOMY
Start date (dd MMM yyyy)	01 AUG 2015
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)	01 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	01 AUG 2015
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)	01 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	CIRRHOSIS
Start date (dd MMM yyyy)	01 AUG 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 AUG 2014
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)	AUG 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Condition	GENERALIZED MUSCLE PAIN
Start date (dd MMM yyyy)	01 JAN 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:37 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:37
Height ( <i>xxx.x</i> )	190.0 cm
Weight ( <i>xxx.x</i> )	130.0 kg
BMI ( <i>xxx.x</i> )	36.01108 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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:39:16

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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** DISABLED

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:39:16

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 110997

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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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)	2 SEP 2020
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:37
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	106 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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)	2 SEP 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:50
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	192 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 16:25 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 16:25

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) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	16:20 (24 HR)
Collection date and time (derived)	2 SEP 2020 16:20

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	2 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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: 09 Jun 2021 16:05:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 SEP 2020 18:11

PC Open Date & Time 02 SEP 2020 16:45

PC Close Date & Time 02 SEP 2020 19:15

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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

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

02 SEP 2020 20:10

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**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 101.9 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 03 SEP 2020 23:44

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 SEP 2020 17:39

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	05 SEP 2020 18:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 06 SEP 2020 16:46

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 07 SEP 2020 17:39

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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

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

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 10 SEP 2020 07:38

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 SEP 2020 17:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 10

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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 11

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



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**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

02 SEP 2020 18:11

PC Open Date & Time

02 SEP 2020 16:45

PC Close Date & Time

02 SEP 2020 19:15

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

02 SEP 2020 20:10

PC Close Date & Time

03 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**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

03 SEP 2020 23:45

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**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

04 SEP 2020 17:40

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 18:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**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

06 SEP 2020 16:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**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

07 SEP 2020 17:40

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

No ☐

Yes ☒

PC Time stamp	02 SEP 2020 18:12
PC Open Date & Time	02 SEP 2020 16:45
PC Close Date & Time	02 SEP 2020 19:15

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 20:10

PC Close Date & Time

03 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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)

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:40
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**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)

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:33
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:47
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**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  
EAB) (1725)

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US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 17:40
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

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EAB) (1725)

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 07:38
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 17:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222462

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222462

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

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*

US3222462

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

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)	2 OCT 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 12:34
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

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)	2 OCT 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:57
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3222462

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 13:26 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 13:26

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

US3222462

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	13:08 (24 HR)
Collection date and time (derived)	2 OCT 2020 13:08



US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:16

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 OCT 2020 13:55

PC Open Date & Time 02 OCT 2020 13:46

PC Close Date & Time 02 OCT 2020 16:16

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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 98.1 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 OCT 2020 18:19

PC Open Date & Time 02 OCT 2020 17:11

PC Close Date & Time 03 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 03 OCT 2020 17:58

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	04 OCT 2020 16:33
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 05 OCT 2020 17:58

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	06 OCT 2020 17:48
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**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

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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

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

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 13:56

PC Open Date & Time

02 OCT 2020 13:46

PC Close Date & Time

02 OCT 2020 16:16

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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

02 OCT 2020 18:19

PC Open Date & Time

02 OCT 2020 17:11

PC Close Date & Time

03 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**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

03 OCT 2020 18:00

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**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

04 OCT 2020 16:34

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:58

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**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

06 OCT 2020 17:49

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:56
PC Open Date & Time	02 OCT 2020 13:46
PC Close Date & Time	02 OCT 2020 16:16

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**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 ☐

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 18:20
PC Open Date & Time	02 OCT 2020 17:11
PC Close Date & Time	03 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**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 ☒

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 16:34
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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  
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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:50
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**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  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Yes ☐

PC Time stamp

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**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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US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222462

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222462

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222462

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3222462

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

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.*

US3222462

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

07:20 (24 HR)

Collection date and time (derived)

28 OCT 2020 07:20

US3222462

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:27

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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="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"/>

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 08:15:25

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 10:12:37
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 08:21:02

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 DEC 2020 09:55:27
Patient Cloud Open Date & Time	18 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 16:12:02

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☒

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 JAN 2021 09:12:58

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 17:37:37

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 21:36:10

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 JAN 2021 06:37:22
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 16:02:04
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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

23 FEB 2021 05:14:39

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 06:37:58

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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

30 MAR 2021 22:11:51

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 <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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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

13 APR 2021 17:59:37

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 19:47:57

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 22:07:04

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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°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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2021 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 390

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐ 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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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°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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2022 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 <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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐ 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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**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 ☐

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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"/>

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3222462

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:02

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		24 MAR 2021 12:12:07

US3222462

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222462

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222462

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222462

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Date of Contact	23 DEC 2020
Time of Contact	09:50
Date and Time of Contact (derived)	23 DEC 2020 09:50
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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"/>

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (1)

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Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 18:39:14

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



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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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Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Symptom Day

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 18:39:14

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

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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



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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

Date	22 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Symptom Day

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.7 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 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Symptom Day

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

Date	24 DEC 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	98 F
-------------	------

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

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

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

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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"/>

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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 23 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

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

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Form: Symptom Log (11)

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Generated On: 09 Jun 2021 16:05:02

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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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 18:39:14

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 18:39:14

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Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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) 22 Feb 2021 18:39:14

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Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Symptom Day

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

Date	02 JAN 2021
------	-------------

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

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

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

Temperature	99.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 14:35:43

Generated On: 09 Jun 2021 16:05:02

Date of Visit 23 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 23 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☐  
Nasal Swab ☒  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 DEC 2020
Day 5	Yes	27 DEC 2020
Day 7	Yes	29 DEC 2020
Day 9	Yes	31 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	10:16 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 10:16
Height ( <i>xxx.x</i> )	190.5 cm
Weight ( <i>xxx.x</i> )	132.2 kg
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	53 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222462

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

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Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 22 Feb 2021 18:39:15

Generated On: 09 Jun 2021 16:05:02

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 DEC 2020

US3222462

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

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3222462

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

Form: Unblinding

Generated On: 09 Jun 2021 16:05:02

Date of updated informed consent ( <i>dd MMM yyyy</i> )		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5	<input type="checkbox"/>
	Amendment 6 or later	<input type="checkbox"/>
Date of unblinding ( <i>dd MMM yyyy</i> )		
Participant randomization assignment	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
Actual Dose 1	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Actual Dose 2	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Will participant receive mRNA-1273?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Placebo Only Flag		
Continuing with mRNA-1273		

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:02

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00 - 23:59</i> )	_____
Collection Date and Time (derived)	_____

US3222462

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 18:39:13

Generated On: 09 Jun 2021 16:05:02

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

AEID	USA-US104-2021-MRNA-1273-P30 1000007
Adverse event	BLADDER INFECTION/ UROSEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT IS CURRENTLY ADMITTED WITH A BLADDER INFECTION. HAS BEEN HOSPITALIZED FOR THE PAST 9 DAYS. WILL REQUEST RECORDS AFTER DISCHARGE.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

---

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication CARIA XT

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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) _____		
Start date completely unknown		True
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) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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 2014	
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"/>

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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"/>

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED MUSCLE PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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)	01 JAN 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication FEVER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

	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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222462

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 18:39:14

Generated On: 09 Jun 2021 16:05:02

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3222462

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:02

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

US3222462

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:02

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 ☐

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

SAEID	USA-US104-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

SAEID	USA-US104-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:34
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

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

SAEID	USA-US104-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/FEB/2021 12:52
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

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:35:44

Generated On: 09 Jun 2021 16:05:02

SAEID	USA-US104-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 09:20
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

US3222462 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222462

Form: Participant Creation

Generated On: 09 Jun 2021 16:05:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'US3222462'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:54:25

US3222462

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:05:51

US3222462

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:54:26

US3222462

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:05:51

US3222462

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'SCRN'	System	02 Sep 2020 20:05:51

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:54:27

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '63'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36



US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'YEARS'	System	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '63'	System	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Male (M)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'I'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36



US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:14:36

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Sep 2020'	System	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2020'	System	02 Sep 2020 20:06:03



US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Amendment 3 (3)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:03

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:54:26

US3222462

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'I'	System	02 Sep 2020 20:06:28

US3222462

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:02

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:28



US3222462

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:17:55

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 19:52:52
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 12:22:14
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:57:14
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 14:19:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 14:19:32
Data point term sent to Coder	System	05 Sep 2020 14:18:38
User entered 'Atrial Fibrillation'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2015'	Amber Vasquez (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2015'	System	05 Sep 2020 14:18:30



US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2015'	System	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:18:30

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 05:05:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 05:05:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:21:33
Data point term sent to Coder	System	05 Sep 2020 14:20:42
User entered 'Allergies, Bactrim'	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2014'	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25



US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2014'	System	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2014'	System	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:20:25

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:00:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 17:00:44
Data point term sent to Coder	System	05 Sep 2020 14:22:43
User entered 'Cholescystectomy'	Amber Vasquez (b) (4)	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2015'	Amber Vasquez (b) (4)	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:21:46



US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2015'	Amber Vasquez (b) (4)	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2015'	System	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2015'	System	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2015'	System	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2015'	System	05 Sep 2020 14:21:46

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:24:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:24:34
Data point term sent to Coder	System	05 Sep 2020 14:23:44
User entered 'Cholecystitis'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08



US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2015'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2015'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2015'	System	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2015'	System	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2015'	System	05 Sep 2020 14:23:08



US3222462

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2015'	System	05 Sep 2020 14:23:08

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis liver - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:25:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 14:25:35
Data point term sent to Coder	System	05 Sep 2020 14:24:47
User entered 'Cirrhosis'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2013'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2013'	System	05 Sep 2020 14:23:51



US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2013'	System	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:23:51

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 19:55:00
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 12:22:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:57:41
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 14:25:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 14:25:35
Data point term sent to Coder	System	05 Sep 2020 14:24:47
User entered 'Hypertension'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Aug 2014'	Amber Vasquez (b) (4)	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:24:10



US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Aug 2014'	System	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2014'	System	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	05 Sep 2020 14:24:10

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 11:40:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 11:40:16
Data point term sent to Coder	System	29 Jan 2021 11:39:22
User entered 'generalized muscle pain'	Alicia Cevera (b) (4)	29 Jan 2021 11:39:07
	(b) (4)	

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '01 Jan 2005'	Alicia Cevera (b) (4)	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Alicia Cevera (b) (4)	29 Jan 2021 11:39:07



US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Alicia Cevera (b) (4)	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Alicia Cevera (b) (4)	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'Jan 2005'	System	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2005'	System	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:05:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered empty.	System	29 Jan 2021 11:39:07

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:25:16



US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '15:37'	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '2 Sep 2020 15:37'	System	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '190.0' cm	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16
DataPoint set to visible.	(b) (4)	
	System	02 Sep 2020 20:06:28

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '130.0' kg	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16
DataPoint set to visible.	(b) (4)	
	System	02 Sep 2020 20:06:28

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered '36.01108'	System	05 Sep 2020 14:25:16
DataPoint set to visible.	System	02 Sep 2020 20:06:28

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'kg/m2'	System	05 Sep 2020 14:25:16
DataPoint set to visible.	System	02 Sep 2020 20:06:28

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:28:13
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:19
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure should be recorded as 'ND' at Screening.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:18:13
User entered '36.9' C	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:25:16



US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	05 Oct 2020 14:08:19
User entered 'Oral (Oral)'	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16
	(b) (4)	

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 14:08:19
User entered '82'	Albert Garcia (b) (4)	05 Sep 2020 14:25:16
	(b) (4)	
	Amber Vasquez (b) (4)	
	(b) (4)	

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'bpm'	System	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 14:08:19
User entered '16'	Albert Garcia (b) (4)	05 Sep 2020 14:25:16
	(b) (4)	

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'breaths/min'	System	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 14:08:19
Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' canceled (Site from System).	Albert Garcia (b) (4)	15 Sep 2020 19:18:24
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	05 Sep 2020 14:25:16
User entered '153'	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'mmHg'	System	05 Sep 2020 14:25:16



US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	05 Oct 2020 14:08:19
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Albert Garcia (b) (4)	05 Oct 2020 14:08:19
canceled (Site from System).	(b) (4)	15 Sep 2020 19:18:22
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	05 Sep 2020 14:25:16
(Site from System).		
User entered '106'	Amber Vasquez (b) (4)	05 Sep 2020 14:25:16
	(b) (4)	

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User entered 'mmHg'	System	05 Sep 2020 14:25:16

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52

US3222462

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52

US3222462

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:26:46

US3222462

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Amber Vasquez (b) (4)	05 Sep 2020 14:26:46

US3222462

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

US3222462

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19



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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

US3222462

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19



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Folder: Screening

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Disabled'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'I'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

US3222462

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

**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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

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)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:08:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:27:19

US3222462

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:19

US3222462

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:06:19

US3222462

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'VISIT1'	System	02 Sep 2020 20:06:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:59:21



US3222462

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '110997'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:59:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:59:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

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)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:01:54
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'CORRECTED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 21:51:43
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 21:51:30
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:33:45

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

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)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:35:00
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	05 Sep 2020 14:29:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:29:20
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 21:51:30

US3222462

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Albert Garcia (b) (4)	04 Sep 2020 21:51:30

US3222462

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Albert Garcia (b) (4)	04 Sep 2020 21:51:30

US3222462

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Query 'Liver Disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:35:03
User opened query 'Liver Disease is recorded as Yes, System but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).		05 Sep 2020 14:29:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:29:20
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 21:51:30

US3222462

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:02

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Albert Garcia (b) (4)	05 Oct 2020 14:03:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:00:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:00:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:32
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' canceled (Site from DM).		25 Sep 2020 13:58:28
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' (Site from DM).		15 Sep 2020 19:18:42
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:58
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:35
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:32
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' canceled (Site from DM).		25 Sep 2020 13:58:28
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' (Site from DM).		15 Sep 2020 19:18:42
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:58
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:35
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '15:37'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Sep 2020 15:37'	System	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '36.9' C	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '82'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'bpm'	System	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'breaths/min'	System	05 Sep 2020 14:31:18



US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '153'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	17 Sep 2020 00:26:24
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Sep 2020 14:31:18
User entered '106'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18
	(b) (4)	

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:56
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:32
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' canceled (Site from DM).		25 Sep 2020 13:58:28
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Temperature should be recorded as 'ND' at Screening.' (Site from DM).		15 Sep 2020 19:18:42
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:27:58
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:08:43
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:58:35
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Please enter the Post-Dose Vital Signs, since data is required on this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:26:31
Query 'Please enter the Post-Dose Vital Signs, since data is required on this form.' answered with (b) (6) (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:23:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:09:44
User opened query 'Please enter the Post-Dose Vital Signs, since data is required on this form.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:19:42
User closed query 'Data is required. Please complete.' (Site from System).		15 Sep 2020 19:19:18
Query 'Data is required. Please complete.' answered with 'Incorrect data was entered' (Site from System).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:47:19
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 14:46:43
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:46:43
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User entered '2 Sep 2020'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 16:25. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' (Site from DM). Query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 16:25. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' answered with 'CORRECT AS ENTERED' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 08:14:53
User opened query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 16:25. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Oct 2020 11:58:18
User entered '16:50' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:27:41
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:09:44
User entered '16:50'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:46:43
	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Sep 2020 16:50'	System	05 Oct 2020 14:09:44
User entered empty.	System	05 Sep 2020 14:46:43
User entered '2 Sep 2020 16:50'	System	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '37.2' C reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User entered '37.2' C	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '88' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User entered '88'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'bpm'	System	05 Oct 2020 14:09:44
User entered empty.	System	05 Sep 2020 14:46:43
User entered 'bpm'	System	05 Sep 2020 14:31:18



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User entered '16'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'breaths/min'	System	05 Oct 2020 14:09:44
User entered empty.	System	05 Sep 2020 14:46:43
User entered 'breaths/min'	System	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '192' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 14:46:43
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	05 Sep 2020 14:46:43
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 14:31:18
User entered '192'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:09:44
User entered empty.	System	05 Sep 2020 14:46:43
User entered 'mmHg'	System	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '104' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:09:44
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 14:46:43
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	05 Sep 2020 14:46:43
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	05 Sep 2020 14:46:43
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 14:31:18
User entered '104'	Amber Vasquez (b) (4)	05 Sep 2020 14:31:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:09:44
User entered empty.	System	05 Sep 2020 14:46:43
User entered 'mmHg'	System	05 Sep 2020 14:31:18

US3222462

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:07:08

US3222462

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:07:08



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

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)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16:25'	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Sep 2020 16:25'	System	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	02 Sep 2020 20:41:11



US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'ONCE'	System	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 20:41:11

US3222462

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:10:14

US3222462

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Sep 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:10:14

US3222462

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16:20'	Albert Garcia (b) (4)	05 Oct 2020 14:10:14

US3222462

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Sep 2020 16:20'	System	05 Oct 2020 14:10:14

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	05 Oct 2020 14:10:37
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	05 Oct 2020 14:10:37
User entered '2 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	05 Oct 2020 14:10:37
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	05 Oct 2020 14:10:28
User entered '2 Oct 2020'	System	05 Oct 2020 14:10:28
	Albert Garcia (b) (4)	05 Oct 2020 14:10:28
	(b) (4)	

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:10:28



US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16:15'	Albert Garcia (b) (4)	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Sep 2020 16:15'	System	05 Oct 2020 14:10:37
User entered '2 Oct 2020 16:15'	System	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Albert Garcia (b) (4)	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Albert Garcia (b) (4)	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	05 Oct 2020 14:10:28

US3222462

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:38:58



US3222462

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	02 Oct 2020 17:38:58

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:10:36', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered 'Yes (Y)'	System	02 Sep 2020 22:11:17

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:10:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered '98.8'	System	02 Sep 2020 22:11:17

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:10:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered 'Yes (Y)'	System	02 Sep 2020 22:11:17

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 12:09:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:57:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Sep 2020 22:11:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered '1'	System	02 Sep 2020 22:11:17

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered '0'	System	02 Sep 2020 22:11:17

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c0f57e87-e747-47d8-998d-586ab2305e7c'	System	02 Sep 2020 22:11:17
User entered '02 Sep 2020 18:11'	System	02 Sep 2020 22:11:17



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 16:45'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 19:15'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 2'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc'	System	04 Sep 2020 03:44:56
User entered 'Yes (Y)'	System	04 Sep 2020 03:44:56

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:31', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc' User entered '101.9'	System	04 Sep 2020 03:44:56
	System	04 Sep 2020 03:44:56

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc'	System	04 Sep 2020 03:44:56
User entered 'Yes (Y)'	System	04 Sep 2020 03:44:56

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Comment added 'pt did take ibuprofen for fever as stated in diary previous entry was transcript error'. User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		12 Nov 2020 19:15:06
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 12:09:51
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:57:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Sep 2020 03:44:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc'	System	04 Sep 2020 03:44:56
User entered '1'	System	04 Sep 2020 03:44:56



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc'	System	04 Sep 2020 03:44:56
User entered '0'	System	04 Sep 2020 03:44:56

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:44:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a39f5b0f-686a-4f30-b84b-89dadec034cc'	System	04 Sep 2020 03:44:56
User entered '03 Sep 2020 23:44'	System	04 Sep 2020 03:44:56

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 3'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:12', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered 'Yes (Y)'	System	04 Sep 2020 21:39:38

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered '98.1'	System	04 Sep 2020 21:39:38

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:26', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered 'Yes (Y)'	System	04 Sep 2020 21:39:38



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 12:09:57
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:57:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Sep 2020 21:39:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered '1'	System	04 Sep 2020 21:39:38

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered '0'	System	04 Sep 2020 21:39:38

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7d92743b-749b-4182-9c37-7e7848e93549'	System	04 Sep 2020 21:39:38
User entered '04 Sep 2020 17:39'	System	04 Sep 2020 21:39:38

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 4'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:31:03', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered 'Yes (Y)'	System	05 Sep 2020 22:32:28

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:10', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered '97.3'	System	05 Sep 2020 22:32:28



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:14', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered 'Yes (Y)'	System	05 Sep 2020 22:32:28

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:33:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:57:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered '1'	System	05 Sep 2020 22:32:28

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered '0'	System	05 Sep 2020 22:32:28

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '755613c8-c4d3-4a12-b8b7-79f3b9f51cb0'	System	05 Sep 2020 22:32:28
User entered '05 Sep 2020 18:32'	System	05 Sep 2020 22:32:28

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 5'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered 'Yes (Y)'	System	06 Sep 2020 20:46:42



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:26', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered '98.5'	System	06 Sep 2020 20:46:42

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered 'Yes (Y)'	System	06 Sep 2020 20:46:42

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 10:33:50
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:58:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 20:46:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered '1'	System	06 Sep 2020 20:46:42

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered '0'	System	06 Sep 2020 20:46:42

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:39', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'be0806f0-369b-4a87-935f-9d52b18c9f99'	System	06 Sep 2020 20:46:42
User entered '06 Sep 2020 16:46'	System	06 Sep 2020 20:46:42

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 6'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered 'Yes (Y)'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered '97.5'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:44', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered 'Yes (Y)'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 10:33:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:58:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:47', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered '1'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:47', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered '0'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:51', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0f7c8501-37fa-438c-a711-128826219043'	System	07 Sep 2020 21:39:57
User entered '07 Sep 2020 17:39'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 7'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	07 Sep 2020 21:39:57
User entered 'Day 8'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:37:59', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered 'Yes (Y)'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:28', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered '96.3'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:31', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered 'Yes (Y)'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 12:10:36
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:58:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Sep 2020 11:38:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:33', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered '1'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:33', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered '0'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:38', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd2789e6-2ed3-4089-9287-ac773e22b961'	System	10 Sep 2020 11:38:41
User entered '10 Sep 2020 07:38'	System	10 Sep 2020 11:38:41



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 11:38:41
User entered 'Day 9'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:46:57', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered 'Yes (Y)'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:47:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered '97.6'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:47:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered 'Yes (Y)'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		30 Oct 2020 12:10:43
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:58:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Sep 2020 21:49:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:48:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered '1'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:48:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered '0'	System	10 Sep 2020 21:49:06



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:49:01', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd3db06d-ab05-47fd-9633-20f157b0e361'	System	10 Sep 2020 21:49:06
User entered '10 Sep 2020 17:49'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 11:38:41
User entered 'Day 10'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 21:49:06
User entered 'Day 11'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fd2a36a2-0ddd-4576-b7c7-8370abd82d32'	System	02 Sep 2020 22:11:42
User entered 'None (1)'	System	02 Sep 2020 22:11:42

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fd2a36a2-0ddd-4576-b7c7-8370abd82d32'	System	02 Sep 2020 22:11:42
User entered 'No (N)'	System	02 Sep 2020 22:11:42



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fd2a36a2-0ddd-4576-b7c7-8370abd82d32'	System	02 Sep 2020 22:11:42
User entered 'No (N)'	System	02 Sep 2020 22:11:42

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fd2a36a2-0ddd-4576-b7c7-8370abd82d32'	System	02 Sep 2020 22:11:42
User entered 'None (1)'	System	02 Sep 2020 22:11:42

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:39', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fd2a36a2-0ddd-4576-b7c7-8370abd82d32'	System	02 Sep 2020 22:11:42
User entered '02 Sep 2020 18:11'	System	02 Sep 2020 22:11:42

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 16:45'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 19:15'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 2'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '88a1e8cd-d35d-414c-b3c9-2e1ef372ea42'	System	04 Sep 2020 03:45:21
User entered 'None (1)'	System	04 Sep 2020 03:45:21

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:05', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '88a1e8cd-d35d-414c-b3c9-2e1ef372ea42'	System	04 Sep 2020 03:45:21
User entered 'No (N)'	System	04 Sep 2020 03:45:21

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:08', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '88a1e8cd-d35d-414c-b3c9-2e1ef372ea42'	System	04 Sep 2020 03:45:21
User entered 'No (N)'	System	04 Sep 2020 03:45:21

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '88a1e8cd-d35d-414c-b3c9-2e1ef372ea42'	System	04 Sep 2020 03:45:21
User entered 'None (1)'	System	04 Sep 2020 03:45:21

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:16', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '88a1e8cd-d35d-414c-b3c9-2e1ef372ea42'	System	04 Sep 2020 03:45:21
User entered '03 Sep 2020 23:45'	System	04 Sep 2020 03:45:21

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 3'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:44', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a99051e3-ddda-4047-be70-1b8818850629'	System	04 Sep 2020 21:40:04
User entered 'None (1)'	System	04 Sep 2020 21:40:04

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a99051e3-ddda-4047-be70-1b8818850629'	System	04 Sep 2020 21:40:04
User entered 'No (N)'	System	04 Sep 2020 21:40:04

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a99051e3-ddda-4047-be70-1b8818850629'	System	04 Sep 2020 21:40:04
User entered 'No (N)'	System	04 Sep 2020 21:40:04

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:39:55', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a99051e3-ddda-4047-be70-1b8818850629'	System	04 Sep 2020 21:40:04
User entered 'None (1)'	System	04 Sep 2020 21:40:04

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a99051e3-ddda-4047-be70-1b8818850629' User entered '04 Sep 2020 17:40'	System	04 Sep 2020 21:40:04
	System	04 Sep 2020 21:40:04

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 4'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7b60a1af-faa4-4384-86b0-cb1848a1281a'	System	05 Sep 2020 22:32:46
User entered 'None (1)'	System	05 Sep 2020 22:32:46

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:31', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7b60a1af-faa4-4384-86b0-cb1848a1281a'	System	05 Sep 2020 22:32:46
User entered 'No (N)'	System	05 Sep 2020 22:32:46

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7b60a1af-faa4-4384-86b0-cb1848a1281a'	System	05 Sep 2020 22:32:46
User entered 'No (N)'	System	05 Sep 2020 22:32:46

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:38', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7b60a1af-faa4-4384-86b0-cb1848a1281a'	System	05 Sep 2020 22:32:46
User entered 'None (1)'	System	05 Sep 2020 22:32:46

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7b60a1af-faa4-4384-86b0-cb1848a1281a'	System	05 Sep 2020 22:32:46
User entered '05 Sep 2020 18:32'	System	05 Sep 2020 22:32:46

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 5'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'ed978bef-e8de-42b4-9f1c-2af8c96dd4d7'	System	06 Sep 2020 20:47:10
User entered 'None (1)'	System	06 Sep 2020 20:47:10

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:53', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'ed978bef-e8de-42b4-9f1c-2af8c96dd4d7'	System	06 Sep 2020 20:47:10
User entered 'No (N)'	System	06 Sep 2020 20:47:10

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:46:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'ed978bef-e8de-42b4-9f1c-2af8c96dd4d7'	System	06 Sep 2020 20:47:10
User entered 'No (N)'	System	06 Sep 2020 20:47:10

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'ed978bef-e8de-42b4-9f1c-2af8c96dd4d7'	System	06 Sep 2020 20:47:10
User entered 'None (1)'	System	06 Sep 2020 20:47:10

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'ed978bef-e8de-42b4-9f1c-2af8c96dd4d7'	System	06 Sep 2020 20:47:10
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:47:10

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 6'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:39:58', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '61ac76ef-1a79-466f-81dd-7f701935b911'	System	07 Sep 2020 21:40:22
User entered 'None (1)'	System	07 Sep 2020 21:40:22

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:03', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '61ac76ef-1a79-466f-81dd-7f701935b911'	System	07 Sep 2020 21:40:22
User entered 'No (N)'	System	07 Sep 2020 21:40:22

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:06', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '61ac76ef-1a79-466f-81dd-7f701935b911'	System	07 Sep 2020 21:40:22
User entered 'No (N)'	System	07 Sep 2020 21:40:22

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:14', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '61ac76ef-1a79-466f-81dd-7f701935b911'	System	07 Sep 2020 21:40:22
User entered 'None (1)'	System	07 Sep 2020 21:40:22

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '61ac76ef-1a79-466f-81dd-7f701935b911'	System	07 Sep 2020 21:40:22
User entered '07 Sep 2020 17:40'	System	07 Sep 2020 21:40:22

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 7'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:11:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:05', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:30', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'None (0)'	System	02 Sep 2020 22:12:51



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered 'Yes (Y)'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-02T18:12:48', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b57fd135-fbfd-42f2-94e2-822186dcec50'	System	02 Sep 2020 22:12:51
User entered '02 Sep 2020 18:12'	System	02 Sep 2020 22:12:51

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 16:45'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 19:15'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 2'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:34', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:37', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'None (0)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered 'No (N)'	System	04 Sep 2020 03:45:50

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-03T23:45:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8e3b989c-baf7-4683-a395-be35e04e38fa'	System	04 Sep 2020 03:45:50
User entered '03 Sep 2020 23:45'	System	04 Sep 2020 03:45:50



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 3'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:09', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:16', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:19', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:24', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'None (0)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered 'No (N)'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-04T17:40:36', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'b4356dd5-736f-4100-884e-9f5f96624a1b'	System	04 Sep 2020 21:40:41
User entered '04 Sep 2020 17:40'	System	04 Sep 2020 21:40:41

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 4'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:53', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:32:59', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:33:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:33:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:33:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'None (0)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:33:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered 'No (N)'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-05T18:33:14', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1e774cc5-2627-47cd-b1c1-8eb26bef3e1c'	System	05 Sep 2020 22:33:19
User entered '05 Sep 2020 18:33'	System	05 Sep 2020 22:33:19

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 5'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:09', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:15', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'None (0)'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered 'No (N)'	System	06 Sep 2020 20:47:35



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-06T16:47:30', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '7c113d0f-3387-4cd1-85b7-34bc4b5f9e6e'	System	06 Sep 2020 20:47:35
User entered '06 Sep 2020 16:47'	System	06 Sep 2020 20:47:35

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 6'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:30', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:37', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:40', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:43', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'None (0)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered 'No (N)'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-07T17:40:55', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f7022221-0332-49f1-9434-81ec211b2851'	System	07 Sep 2020 21:40:59
User entered '07 Sep 2020 17:40'	System	07 Sep 2020 21:40:59

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 7'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:41:11



US3222462

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	07 Sep 2020 21:39:57
User entered 'Day 8'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1ab52453-9f37-4ca3-9163-ce10432347f2'	System	10 Sep 2020 11:38:58
User entered 'No (N)'	System	10 Sep 2020 11:38:58

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T07:38:55', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '1ab52453-9f37-4ca3-9163-ce10432347f2'	System	10 Sep 2020 11:38:58
User entered '10 Sep 2020 07:38'	System	10 Sep 2020 11:38:58

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 21:39:57

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 11:38:41
User entered 'Day 9'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:49:06', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '85034ad4-4138-41f8-ba7c-4bce809df56d'	System	10 Sep 2020 21:49:21
User entered 'No (N)'	System	10 Sep 2020 21:49:21



US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-09-10T17:49:15', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '85034ad4-4138-41f8-ba7c-4bce809df56d'	System	10 Sep 2020 21:49:21
User entered '10 Sep 2020 17:49'	System	10 Sep 2020 21:49:21

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 11:38:41
User entered 'Day 10'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 11:38:41

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 11:38:41



US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	10 Sep 2020 21:49:06
User entered 'Day 11'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 21:49:06

US3222462

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 21:49:06

US3222462

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	08 Oct 2020 20:49:44

US3222462

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '9 Sep 2020'	Crystal Paccione (b) (4)	08 Oct 2020 20:49:44

US3222462

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 20:49:44



US3222462

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 20:49:44

US3222462

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:07

US3222462

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	02 Oct 2020 17:39:07

US3222462

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	08 Oct 2020 20:54:05

US3222462

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16 Sep 2020'	Crystal Paccione (b) (4)	08 Oct 2020 20:54:05

US3222462

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 20:54:05

US3222462

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 20:54:05

US3222462

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:12



US3222462

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	02 Oct 2020 17:39:12

US3222462

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	08 Oct 2020 21:11:30

US3222462

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '23 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 21:11:30

US3222462

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 21:11:30

US3222462

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Crystal Paccione (b) (4)	08 Oct 2020 21:11:30

US3222462

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:17

US3222462

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	02 Oct 2020 17:39:17

US3222462

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:26



US3222462

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '2 Oct 2020'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:26

US3222462

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:26

US3222462

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'VISIT2'	System	02 Oct 2020 17:39:26

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '2 Oct 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '12:34'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Oct 2020 12:34'	System	05 Oct 2020 14:14:07



US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '37.3' C	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '68'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'bpm'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '16'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'breaths/min'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '126'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07



US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '80'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '2 Oct 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '13:57'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Oct 2020 13:57'	System	05 Oct 2020 14:14:07



US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '37.1' C	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '66'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'bpm'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '16'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'breaths/min'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '132'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07



US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '85'	Albert Garcia (b) (4)	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'mmHg'	System	05 Oct 2020 14:14:07

US3222462

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:15

US3222462

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Oct 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:14:15

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

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)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45



US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Oct 2020'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '13:26'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Oct 2020 13:26'	System	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'ONCE'	System	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 17:39:45

US3222462

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:29



US3222462

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Oct 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:14:29

US3222462

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '13:08'	Albert Garcia (b) (4)	05 Oct 2020 14:14:29

US3222462

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Oct 2020 13:08'	System	05 Oct 2020 14:14:29

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '2 Oct 2020'	Albert Garcia (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '13:13'	Albert Garcia (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '2 Oct 2020 13:13'	System	05 Oct 2020 14:14:41



US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	Albert Garcia (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Albert Garcia (b) (4)	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	05 Oct 2020 14:14:41

US3222462

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	02 Oct 2020 17:39:50

US3222462

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	02 Oct 2020 17:39:50

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:54:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered 'Yes (Y)'	System	02 Oct 2020 17:55:32



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered '98.8'	System	02 Oct 2020 17:55:32

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered 'Yes (Y)'	System	02 Oct 2020 17:55:32

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 14:02:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 11:58:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered '1'	System	02 Oct 2020 17:55:32

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered '0'	System	02 Oct 2020 17:55:32

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3a651e3c-273c-47f6-a35b-e930881c01a6'	System	02 Oct 2020 17:55:32
User entered '02 Oct 2020 13:55'	System	02 Oct 2020 17:55:32

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 13:46'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 16:16'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:18:51', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	System	02 Oct 2020 22:19:12
User entered 'Yes (Y)'	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:18:57', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	System	02 Oct 2020 22:19:12
User entered '98.1'	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:01', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	System	02 Oct 2020 22:19:12
User entered 'Yes (Y)'	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 14:02:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:59:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	(b) (4)	
User entered '1'	System	02 Oct 2020 22:19:12
	System	02 Oct 2020 22:19:12
	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	System	02 Oct 2020 22:19:12
User entered '0'	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:08', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '624bae4d-bfb4-4009-a85f-e5657316a5df'	System	02 Oct 2020 22:19:12
User entered '02 Oct 2020 18:19'	System	02 Oct 2020 22:19:12

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 17:11'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 2'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:34', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	System	03 Oct 2020 21:58:56
User entered 'Yes (Y)'	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	System	03 Oct 2020 21:58:56
User entered '98.3'	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	System	03 Oct 2020 21:58:56
User entered 'Yes (Y)'	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4)	01 Nov 2020 14:02:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:59:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	(b) (4)	
User entered '1'	System	03 Oct 2020 21:58:56
	System	03 Oct 2020 21:58:56
	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	System	03 Oct 2020 21:58:56
User entered '0'	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:58:53', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '3e011a63-7674-4571-afe9-ff5d6b9a0c52'	System	03 Oct 2020 21:58:56
User entered '03 Oct 2020 17:58'	System	03 Oct 2020 21:58:56

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 3'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	System	04 Oct 2020 20:33:57
User entered 'Yes (Y)'	System	04 Oct 2020 20:33:57

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	System	04 Oct 2020 20:33:57
User entered '98.7'	System	04 Oct 2020 20:33:57

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:45', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	System	04 Oct 2020 20:33:57
User entered 'Yes (Y)'	System	04 Oct 2020 20:33:57

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 14:02:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:59:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:48', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	(b) (4)	
User entered '1'	System	04 Oct 2020 20:33:57
	System	04 Oct 2020 20:33:57
	System	04 Oct 2020 20:33:57

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:48', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	System	04 Oct 2020 20:33:57
User entered '0'	System	04 Oct 2020 20:33:57

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:33:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0bf3dd61-89e7-4877-8c9d-798f3b0a0756'	System	04 Oct 2020 20:33:57
User entered '04 Oct 2020 16:33'	System	04 Oct 2020 20:33:57



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 4'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:57:41', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	System	05 Oct 2020 21:58:08
User entered 'Yes (Y)'	System	05 Oct 2020 21:58:08

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:57:50', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	System	05 Oct 2020 21:58:08
User entered '98.4'	System	05 Oct 2020 21:58:08

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:57:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	System	05 Oct 2020 21:58:08
User entered 'Yes (Y)'	System	05 Oct 2020 21:58:08

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 14:02:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:57:58', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	(b) (4)	
User entered '1'	System	05 Oct 2020 21:58:08
	System	05 Oct 2020 21:58:08
	System	05 Oct 2020 21:58:08

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:57:58', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	System	05 Oct 2020 21:58:08
User entered '0'	System	05 Oct 2020 21:58:08



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4d25b73e-39d6-4ce4-817b-28ac7f72aeaa'	System	05 Oct 2020 21:58:08
User entered '05 Oct 2020 17:58'	System	05 Oct 2020 21:58:08

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 5'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:47:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	System	06 Oct 2020 21:48:33
User entered 'Yes (Y)'	System	06 Oct 2020 21:48:33

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	System	06 Oct 2020 21:48:33
User entered '98.3'	System	06 Oct 2020 21:48:33

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	System	06 Oct 2020 21:48:33
User entered 'Yes (Y)'	System	06 Oct 2020 21:48:33

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PT WAS MISTAKENLY REPORTING THEIR USUAL DAILY MEDICATION.' (Site from System).	(b) (4)	01 Nov 2020 14:02:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	24 Oct 2020 11:59:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	(b) (4)	
User entered '1'	System	06 Oct 2020 21:48:33
	System	06 Oct 2020 21:48:33
	System	06 Oct 2020 21:48:33



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	System	06 Oct 2020 21:48:33
User entered '0'	System	06 Oct 2020 21:48:33

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:30', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '4a5639ed-8d7a-450f-b760-0f559a26933e'	System	06 Oct 2020 21:48:33
User entered '06 Oct 2020 17:48'	System	06 Oct 2020 21:48:33

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 6'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 7'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:42', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '6900cb66-ad97-4478-b54c-a32bbfa73b2f'	System	02 Oct 2020 17:56:07
User entered 'None (1)'	System	02 Oct 2020 17:56:07



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '6900cb66-ad97-4478-b54c-a32bbfa73b2f'	System	02 Oct 2020 17:56:07
User entered 'No (N)'	System	02 Oct 2020 17:56:07

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '6900cb66-ad97-4478-b54c-a32bbfa73b2f'	System	02 Oct 2020 17:56:07
User entered 'No (N)'	System	02 Oct 2020 17:56:07

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:55:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '6900cb66-ad97-4478-b54c-a32bbfa73b2f'	System	02 Oct 2020 17:56:07
User entered 'None (1)'	System	02 Oct 2020 17:56:07

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:01', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '6900cb66-ad97-4478-b54c-a32bbfa73b2f'	System	02 Oct 2020 17:56:07
User entered '02 Oct 2020 13:56'	System	02 Oct 2020 17:56:07

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 13:46'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 16:16'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:15', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a5347a76-53ec-435e-b4cf-28bda863f8c2'	System	02 Oct 2020 22:19:35
User entered 'None (1)'	System	02 Oct 2020 22:19:35



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:19', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a5347a76-53ec-435e-b4cf-28bda863f8c2'	System	02 Oct 2020 22:19:35
User entered 'No (N)'	System	02 Oct 2020 22:19:35

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a5347a76-53ec-435e-b4cf-28bda863f8c2'	System	02 Oct 2020 22:19:35
User entered 'No (N)'	System	02 Oct 2020 22:19:35

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a5347a76-53ec-435e-b4cf-28bda863f8c2'	System	02 Oct 2020 22:19:35
User entered 'None (1)'	System	02 Oct 2020 22:19:35

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a5347a76-53ec-435e-b4cf-28bda863f8c2'	System	02 Oct 2020 22:19:35
User entered '02 Oct 2020 18:19'	System	02 Oct 2020 22:19:35

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 17:11'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 2'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:59:19', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '9ee310c4-ca73-40b0-94ae-5e4b7821342b'	System	03 Oct 2020 22:00:11
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 22:00:11



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:59:23', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '9ee310c4-ca73-40b0-94ae-5e4b7821342b'	System	03 Oct 2020 22:00:11
User entered 'No (N)'	System	03 Oct 2020 22:00:11

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T17:59:51', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '9ee310c4-ca73-40b0-94ae-5e4b7821342b'	System	03 Oct 2020 22:00:11
User entered 'No (N)'	System	03 Oct 2020 22:00:11

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:01', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '9ee310c4-ca73-40b0-94ae-5e4b7821342b'	System	03 Oct 2020 22:00:11
User entered 'None (1)'	System	03 Oct 2020 22:00:11

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:05', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '9ee310c4-ca73-40b0-94ae-5e4b7821342b'	System	03 Oct 2020 22:00:11
User entered '03 Oct 2020 18:00'	System	03 Oct 2020 22:00:11

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 3'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a157bd07-7e23-47ea-a130-3682827c1516'	System	04 Oct 2020 20:34:18
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 20:34:18



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a157bd07-7e23-47ea-a130-3682827c1516'	System	04 Oct 2020 20:34:18
User entered 'No (N)'	System	04 Oct 2020 20:34:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:08', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a157bd07-7e23-47ea-a130-3682827c1516'	System	04 Oct 2020 20:34:18
User entered 'No (N)'	System	04 Oct 2020 20:34:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:12', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a157bd07-7e23-47ea-a130-3682827c1516'	System	04 Oct 2020 20:34:18
User entered 'None (1)'	System	04 Oct 2020 20:34:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:15', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a157bd07-7e23-47ea-a130-3682827c1516'	System	04 Oct 2020 20:34:18
User entered '04 Oct 2020 16:34'	System	04 Oct 2020 20:34:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 4'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:14', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2bb3eba4-8256-45d7-ae77-897b4c50a70c'	System	05 Oct 2020 21:58:37
User entered 'None (1)'	System	05 Oct 2020 21:58:37



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2bb3eba4-8256-45d7-ae77-897b4c50a70c'	System	05 Oct 2020 21:58:37
User entered 'No (N)'	System	05 Oct 2020 21:58:37

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2bb3eba4-8256-45d7-ae77-897b4c50a70c'	System	05 Oct 2020 21:58:37
User entered 'No (N)'	System	05 Oct 2020 21:58:37

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2bb3eba4-8256-45d7-ae77-897b4c50a70c'	System	05 Oct 2020 21:58:37
User entered 'None (1)'	System	05 Oct 2020 21:58:37

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:33', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2bb3eba4-8256-45d7-ae77-897b4c50a70c' User entered '05 Oct 2020 17:58'	System	05 Oct 2020 21:58:37
	System	05 Oct 2020 21:58:37

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 5'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:43', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '707e2e66-df03-4d64-823b-464331c06b37'	System	06 Oct 2020 21:49:18
User entered 'None (1)'	System	06 Oct 2020 21:49:18



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:48:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '707e2e66-df03-4d64-823b-464331c06b37'	System	06 Oct 2020 21:49:18
User entered 'No (N)'	System	06 Oct 2020 21:49:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '707e2e66-df03-4d64-823b-464331c06b37'	System	06 Oct 2020 21:49:18
User entered 'No (N)'	System	06 Oct 2020 21:49:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '707e2e66-df03-4d64-823b-464331c06b37'	System	06 Oct 2020 21:49:18
User entered 'None (1)'	System	06 Oct 2020 21:49:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:15', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '707e2e66-df03-4d64-823b-464331c06b37'	System	06 Oct 2020 21:49:18
User entered '06 Oct 2020 17:49'	System	06 Oct 2020 21:49:18

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 6'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 7'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:10', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:13', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'None (0)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:28', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered 'No (N)'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T13:56:34', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'abf0125b-8f5a-4ff3-a20a-2649477cf2ae'	System	02 Oct 2020 17:56:38
User entered '02 Oct 2020 13:56'	System	02 Oct 2020 17:56:38

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 13:46'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 16:16'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:40', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:43', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:51', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'None (0)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:19:59', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered 'No (N)'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-02T18:20:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '8402adc2-f7e7-4879-9b2e-488d7519a4d7'	System	02 Oct 2020 22:20:06
User entered '02 Oct 2020 18:20'	System	02 Oct 2020 22:20:06

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '02 Oct 2020 17:11'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 2'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:14', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:18', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:24', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'None (0)'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:33', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered 'No (N)'	System	03 Oct 2020 22:00:39



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-03T18:00:37', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '44836ec1-cbf2-47e4-8f97-f283ecb2e886'	System	03 Oct 2020 22:00:39
User entered '03 Oct 2020 18:00'	System	03 Oct 2020 22:00:39

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 3'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:24', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:26', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:31', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:33', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'None (0)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:36', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered 'No (N)'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-04T16:34:39', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'a4ee7041-fb4b-479c-a3f3-7f6b03be0fae'	System	04 Oct 2020 20:34:44
User entered '04 Oct 2020 16:34'	System	04 Oct 2020 20:34:44

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 4'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:44', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:47', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:49', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:58:57', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'None (0)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:59:03', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered 'No (N)'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-05T17:59:07', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd330b4b4-0fa3-4ff8-a9a5-ac84be5ae789'	System	05 Oct 2020 21:59:12
User entered '05 Oct 2020 17:59'	System	05 Oct 2020 21:59:12

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 5'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:35', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:40', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:44', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:48', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:51', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'None (0)'	System	06 Oct 2020 21:50:08



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:49:59', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered 'No (N)'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (feca8bbadd9462d9)', Time: '2020-10-06T17:50:05', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f4f260b8-bc7a-4c89-9b13-f1d831cc121b'	System	06 Oct 2020 21:50:08
User entered '06 Oct 2020 17:50'	System	06 Oct 2020 21:50:08

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 6'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
Data entry locked.	System	02 Oct 2020 17:39:45
User entered 'Day 7'	System	02 Oct 2020 17:39:45



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13



US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:39:45

US3222462

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:57:13
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:39:45

US3222462

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	19 Oct 2020 12:25:55

US3222462

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '9 Oct 2020'	Albert Garcia (b) (4)	19 Oct 2020 12:25:55

US3222462

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	19 Oct 2020 12:25:55

US3222462

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Albert Garcia (b) (4)	19 Oct 2020 12:25:55

US3222462

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	19 Oct 2020 12:26:55

US3222462

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	19 Oct 2020 12:26:55



US3222462

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:04:39

US3222462

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '16 Oct 2020'	Albert Garcia (b) (4)	24 Oct 2020 12:04:39

US3222462

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	24 Oct 2020 12:04:39

US3222462

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Oct 2020 12:04:39

US3222462

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:04:45

US3222462

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	24 Oct 2020 12:04:45

US3222462

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:04:57

US3222462

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '23 Oct 2020'	Albert Garcia (b) (4)	24 Oct 2020 12:04:57



US3222462

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	24 Oct 2020 12:04:57

US3222462

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Oct 2020 12:04:57

US3222462

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:05:09

US3222462

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	24 Oct 2020 12:05:09

US3222462

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:22

US3222462

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '28 Oct 2020'	Albert Garcia (b) (4)	28 Oct 2020 11:46:22

US3222462

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:22

US3222462

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'VISIT3'	System	28 Oct 2020 11:46:22



US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'No (N)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28



US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered empty.	System	28 Oct 2020 11:46:28

US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22



US3222462

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22

US3222462

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'No (N)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:32

US3222462

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:46:32

US3222462

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:48

US3222462

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '28 Oct 2020'	Albert Garcia (b) (4)	28 Oct 2020 11:46:48

US3222462

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered '07:20'	Albert Garcia (b) (4)	28 Oct 2020 11:46:48

US3222462

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered '28 Oct 2020 07:20'	System	28 Oct 2020 11:46:48

US3222462

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:27
User entered 'Yes (Y)'	Albert Garcia (b) (4)	28 Oct 2020 11:46:55



US3222462

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	28 Oct 2020 11:46:55

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 64'	System	02 Sep 2020 20:41:11

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 20:41:11

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 71'	System	02 Sep 2020 20:41:11

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 20:41:11



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 20:41:11

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered 'Day 78'	System	02 Sep 2020 20:41:11

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47



US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Please 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)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 20:41:11

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:55:47
Data entry locked.	System	02 Sep 2020 20:41:11
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 20:41:11

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2020-11-23T08:15:17', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '93f80e59-cb84-4516-a6d1-e01ac7d7bf21'	System	23 Nov 2020 13:15:30
User entered 'No (N)'	System	23 Nov 2020 13:15:30

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2020-11-23T08:15:21', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '93f80e59-cb84-4516-a6d1-e01ac7d7bf21'	System	23 Nov 2020 13:15:30
User entered 'No (N)'	System	23 Nov 2020 13:15:30



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-11-23T08:15:25', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '93f80e59-cb84-4516-a6d1-e01ac7d7bf21'	System	23 Nov 2020 13:15:30
User entered '23 Nov 2020 08:15:25'	System	23 Nov 2020 13:15:30

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2020-12-01T10:12:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c3e788f1-a0ae-43a0-8726-d9289e393bcc'	System	01 Dec 2020 15:12:42
User entered 'No (N)'	System	01 Dec 2020 15:12:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2020-12-01T10:12:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c3e788f1-a0ae-43a0-8726-d9289e393bcc'	System	01 Dec 2020 15:12:42
User entered 'No (N)'	System	01 Dec 2020 15:12:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-01T10:12:37', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'c3e788f1-a0ae-43a0-8726-d9289e393bcc' User entered '01 Dec 2020 10:12:37'	System	01 Dec 2020 15:12:42
	System	01 Dec 2020 15:12:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2020-12-11T08:20:52', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '76ec4a1c-b6a5-43a3-b058-ea6a4f55aa31'	System	11 Dec 2020 13:21:09
User entered 'No (N)'	System	11 Dec 2020 13:21:09

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2020-12-11T08:20:56', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '76ec4a1c-b6a5-43a3-b058-ea6a4f55aa31'	System	11 Dec 2020 13:21:09
User entered 'No (N)'	System	11 Dec 2020 13:21:09

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-11T08:21:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '76ec4a1c-b6a5-43a3-b058-ea6a4f55aa31'	System	11 Dec 2020 13:21:09
User entered '11 Dec 2020 08:21:02'	System	11 Dec 2020 13:21:09



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2020-12-18T09:38:32', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'Yes (Y)'	System	18 Dec 2020 14:55:39

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2020-12-18T09:38:38', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'No (N)'	System	18 Dec 2020 14:55:39

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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)
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'patient seen for convalescent visit on 12/23/20. tested negative for COVID' (Site from DM). User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:32:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:39:03', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'Yes (Y)'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa' User entered '0'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa' User entered '0'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '0'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '0'	System	18 Dec 2020 14:55:39



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '0'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '0'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa' User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:47:20', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '1'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:54:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 14:55:39



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:55:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'Yes (Y)'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:55:12', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-18T09:55:27', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '60254a16-72f9-4665-bfa0-2ceb63564baa'	System	18 Dec 2020 14:55:39
User entered '18 Dec 2020 09:55:27'	System	18 Dec 2020 14:55:39

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2020-12-26T16:11:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '5802a8e8-c842-4de4-8ccc-8135cc18dc5c'	System	26 Dec 2020 21:12:09
User entered 'No (N)'	System	26 Dec 2020 21:12:09

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2020-12-26T16:11:57', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '5802a8e8-c842-4de4-8ccc-8135cc18dc5c'	System	26 Dec 2020 21:12:09
User entered 'No (N)'	System	26 Dec 2020 21:12:09



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2020-12-26T16:12:02', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '5802a8e8-c842-4de4-8ccc-8135cc18dc5c'	System	26 Dec 2020 21:12:09
User entered '26 Dec 2020 16:12:02'	System	26 Dec 2020 21:12:09

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-01-02T09:12:50', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2b8b62b9-ce32-4e56-b44f-fa0e39cea7e4'	System	02 Jan 2021 14:13:01
User entered 'No (N)'	System	02 Jan 2021 14:13:01

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-01-02T09:12:53', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2b8b62b9-ce32-4e56-b44f-fa0e39cea7e4'	System	02 Jan 2021 14:13:01
User entered 'No (N)'	System	02 Jan 2021 14:13:01

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-02T09:12:58', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '2b8b62b9-ce32-4e56-b44f-fa0e39cea7e4'	System	02 Jan 2021 14:13:01
User entered '02 Jan 2021 09:12:58'	System	02 Jan 2021 14:13:01

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:55:47

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 (5e8ffb82dee22b6e)', Time: '2021-01-15T17:37:26', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '86a6960f-2055-4659-bf64-92c103f7724a'	System	15 Jan 2021 22:37:42
User entered 'No (N)'	System	15 Jan 2021 22:37:42

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-01-15T17:37:29', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '86a6960f-2055-4659-bf64-92c103f7724a'	System	15 Jan 2021 22:37:42
User entered 'No (N)'	System	15 Jan 2021 22:37:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-15T17:37:37', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '86a6960f-2055-4659-bf64-92c103f7724a'	System	15 Jan 2021 22:37:42
User entered '15 Jan 2021 17:37:37'	System	15 Jan 2021 22:37:42



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-01-24T21:35:48', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '27e554c8-6a8d-4721-997c-105dca1a4243'	System	25 Jan 2021 02:36:13
User entered 'No (N)'	System	25 Jan 2021 02:36:13

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-01-24T21:35:53', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '27e554c8-6a8d-4721-997c-105dca1a4243'	System	25 Jan 2021 02:36:13
User entered 'No (N)'	System	25 Jan 2021 02:36:13

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-24T21:36:10', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '27e554c8-6a8d-4721-997c-105dca1a4243'	System	25 Jan 2021 02:36:13
User entered '24 Jan 2021 21:36:10'	System	25 Jan 2021 02:36:13

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-01-29T06:36:46', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea'	System	29 Jan 2021 11:37:33
User entered 'Yes (Y)'	System	29 Jan 2021 11:37:33

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-01-29T06:36:50', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea'	System	29 Jan 2021 11:37:33
User entered 'No (N)'	System	29 Jan 2021 11:37:33

US3222462

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-29T06:36:57', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea'	System	29 Jan 2021 11:37:33
User entered 'No (N)'	System	29 Jan 2021 11:37:33

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-29T06:37:11', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea'	System	29 Jan 2021 11:37:33
User entered 'Yes (Y)'	System	29 Jan 2021 11:37:33

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-29T06:37:18', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea'	System	29 Jan 2021 11:37:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 11:37:33

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-01-29T06:37:22', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'bde55450-89a3-4db0-a36a-54a5b5c3abea' User entered '29 Jan 2021 06:37:22'	System	29 Jan 2021 11:37:33

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-02-12T16:01:54', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '30117c82-4aa2-4128-b542-b8c21101b67b'	System	12 Feb 2021 21:02:09
User entered 'No (N)'	System	12 Feb 2021 21:02:09

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-02-12T16:01:58', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '30117c82-4aa2-4128-b542-b8c21101b67b'	System	12 Feb 2021 21:02:09
User entered 'No (N)'	System	12 Feb 2021 21:02:09

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-02-12T16:02:04', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '30117c82-4aa2-4128-b542-b8c21101b67b'	System	12 Feb 2021 21:02:09
User entered '12 Feb 2021 16:02:04'	System	12 Feb 2021 21:02:09



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:55:47

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 (5e8ffb82dee22b6e)', Time: '2021-02-23T05:14:32-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '79012e8c-e5e4-44ee-b90d-040eb2593a49'	System	23 Feb 2021 10:14:42
User entered 'No (N)'	System	23 Feb 2021 10:14:42

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-02-23T05:14:35-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '79012e8c-e5e4-44ee-b90d-040eb2593a49'	System	23 Feb 2021 10:14:42
User entered 'No (N)'	System	23 Feb 2021 10:14:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-02-23T05:14:39-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '79012e8c-e5e4-44ee-b90d-040eb2593a49' User entered '23 Feb 2021 05:14:39'	System	23 Feb 2021 10:14:42
	System	23 Feb 2021 10:14:42

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-03-13T06:37:44-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd07c5ada-04c7-4fa2-bd52-cc97c34e36ca'	System	13 Mar 2021 11:38:02
User entered 'No (N)'	System	13 Mar 2021 11:38:02



US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-03-13T06:37:52-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd07c5ada-04c7-4fa2-bd52-cc97c34e36ca'	System	13 Mar 2021 11:38:02
User entered 'No (N)'	System	13 Mar 2021 11:38:02

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-03-13T06:37:58-05:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'd07c5ada-04c7-4fa2-bd52-cc97c34e36ca' User entered '13 Mar 2021 06:37:58'	System	13 Mar 2021 11:38:02
	System	13 Mar 2021 11:38:02

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-03-30T22:11:41-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd367d46-df1a-41e0-9fdd-6f9c85e86c2d'	System	31 Mar 2021 02:11:58
User entered 'No (N)'	System	31 Mar 2021 02:11:58

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-03-30T22:11:46-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd367d46-df1a-41e0-9fdd-6f9c85e86c2d'	System	31 Mar 2021 02:11:58
User entered 'No (N)'	System	31 Mar 2021 02:11:58

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-03-30T22:11:51-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'cd367d46-df1a-41e0-9fdd-6f9c85e86c2d' User entered '30 Mar 2021 22:11:51'	System	31 Mar 2021 02:11:58
	System	31 Mar 2021 02:11:58

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-04-13T17:59:29-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0e0a2270-5af3-477a-bede-aaa63905e1b7'	System	13 Apr 2021 21:59:43
User entered 'No (N)'	System	13 Apr 2021 21:59:43

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-04-13T17:59:33-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0e0a2270-5af3-477a-bede-aaa63905e1b7'	System	13 Apr 2021 21:59:43
User entered 'No (N)'	System	13 Apr 2021 21:59:43

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-04-13T17:59:37-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '0e0a2270-5af3-477a-bede-aaa63905e1b7'	System	13 Apr 2021 21:59:43
User entered '13 Apr 2021 17:59:37'	System	13 Apr 2021 21:59:43

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:55:47

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

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 (5e8ffb82dee22b6e)', Time: '2021-04-25T19:47:51-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f6631dd9-b99d-4566-baca-c5ae8819de2c' User entered 'No (N)'	System	25 Apr 2021 23:48:03
	System	25 Apr 2021 23:48:03

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-04-25T19:47:54-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f6631dd9-b99d-4566-baca-c5ae8819de2c'	System	25 Apr 2021 23:48:03
User entered 'No (N)'	System	25 Apr 2021 23:48:03

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-04-25T19:47:57-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'f6631dd9-b99d-4566-baca-c5ae8819de2c'	System	25 Apr 2021 23:48:03
User entered '25 Apr 2021 19:47:57'	System	25 Apr 2021 23:48:03

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[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 (5e8ffb82dee22b6e)', Time: '2021-04-30T22:06:57-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '81486e3b-38e8-485d-8c57-44ad1e1c645c'	System	01 May 2021 02:07:59
User entered 'No (N)'	System	01 May 2021 02:07:59

US3222462

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:02

Have you been exposed to someone with 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 (5e8ffb82dee22b6e)', Time: '2021-04-30T22:07:01-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '81486e3b-38e8-485d-8c57-44ad1e1c645c'	System	01 May 2021 02:07:59
User entered 'No (N)'	System	01 May 2021 02:07:59

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-04-30T22:07:04-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: '81486e3b-38e8-485d-8c57-44ad1e1c645c' User entered '30 Apr 2021 22:07:04'	System	01 May 2021 02:07:59
	System	01 May 2021 02:07:59

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:55:47

US3222462

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:55:47

US3222462

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:55:47



**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:55:47

**US3222462**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:55:47
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:55:47

US3222462

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:05:02**

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)	25 Apr 2021 07:06:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-03-24T12:12:00-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fc4579ba-3ae2-4ebb-9d41-78fe5c8299ad'	System	24 Mar 2021 16:20:12
User entered 'No (N)'	System	24 Mar 2021 16:20:12

US3222462

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:05:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:06:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5e8ffb82dee22b6e)', Time: '2021-03-24T12:12:07-04:00', User OID: 'PatientReportedOutcome (US3222462)', ODM File OID: 'fc4579ba-3ae2-4ebb-9d41-78fe5c8299ad' User entered '24 Mar 2021 12:12:07'	System	24 Mar 2021 16:20:12
	System	24 Mar 2021 16:20:12

US3222462

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	heather jackson (b) (4)	16 Dec 2020 15:45:56

US3222462

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '25 Nov 2020'	heather jackson (b) (4)	16 Dec 2020 15:45:56

US3222462

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	16 Dec 2020 15:45:56

US3222462

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	heather jackson (b) (4)	16 Dec 2020 15:45:56



US3222462

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	heather jackson (b) (4)	16 Dec 2020 15:45:59

US3222462

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 23:42:22
User entered 'I'	System	16 Dec 2020 15:45:59

US3222462

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:59:39

US3222462

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4)	18 Jan 2021 20:59:47
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	18 Jan 2021 20:59:47
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 20:59:47
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	18 Jan 2021 20:59:39
User entered '16 Dec 2020'	(b) (4), (b) (6)	18 Jan 2021 20:59:39

US3222462

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:59:39

US3222462

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:59:39

US3222462

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:13:07

US3222462

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:09:32
User entered 'I'	System	18 Jan 2021 21:13:07



US3222462

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered 'Yes (Y)'	douglas winter (b) (4)	29 Mar 2021 18:52:11

US3222462

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered '28 Jan 2021'	(b) (4) douglas winter (b) (4) (b) (4)	29 Mar 2021 18:52:11

US3222462

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4)	29 Mar 2021 18:52:11

US3222462

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered empty.	douglas winter (b) (4)	29 Mar 2021 18:52:11

US3222462

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered 'Yes (Y)'	douglas winter (b) (4)	29 Mar 2021 18:52:41

US3222462

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:17:16
User entered 'I'	System	29 Mar 2021 18:52:41

US3222462

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	01 Apr 2021 03:07:59
	(b) (4)	

US3222462

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Apr 2021 03:07:59
	(b) (4)	



US3222462

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Apr 2021 03:07:59
	(b) (4)	

US3222462

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
User entered empty.	douglas winter (b) (4)	01 Apr 2021 03:07:59
	(b) (4)	

US3222462

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	01 Apr 2021 03:10:59
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	01 Apr 2021 03:08:03
	(b) (4)	

**US3222462**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:05:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 03:10:59
User entered '1'	System	01 Apr 2021 03:08:03

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:54
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:41:35

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:54
User entered '09:50'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:41:35

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:35
User entered '23 Dec 2020 09:50'	System	23 Dec 2020 19:41:35

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:02

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:54
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	-douglas winter (b) (4) (b) (4)	23 Dec 2020 19:41:35



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:35
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:04:54
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:41:35

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 1 (Day 1)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered '18 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered 'I'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered empty.	System	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:13
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:15

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 2 (Day 2)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered '19 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered 'l'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered empty.	System	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:15
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 3 (Day 3)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered '20 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered 'l'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered empty.	System	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:18
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:52:46

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 4 (Day 4)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered '21 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered 'l'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered empty.	System	23 Dec 2020 19:54:17



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:54:17

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 5 (Day 5)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered '22 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered 'l'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered empty.	System	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:26:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:55:29

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 6 (Day 6)'	(b) (4) douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '36.7' C	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:56:57

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 7 (Day 7)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '24 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 8 (Day 8)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '25 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99.1' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 9 (Day 9)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '26 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98.1' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 10 (Day 10)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '27 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98.4' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 11 (Day 11)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '28 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 12 (Day 12)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '29 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99.3' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:29:48
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:29:54
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:29:57
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 13 (Day 13)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '30 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '97'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99.3' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 14 (Day 14)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '31 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99.1' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 15 (Day 15)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '01 Jan 2021'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Day 16 (Day 16)'	(b) (4) douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '02 Jan 2021'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '0'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '98'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User entered '%'	System	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered '99.1' F	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:05:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:45
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:31:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:05:04

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 12:57:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 12:57:26
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Jan 2021 12:57:26
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 19:57:25
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).		17 Feb 2021 10:34:15
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'THERE ISN'T A SALIVA SAMPLE AT ILLNESS VISIT DAY 1.' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 23:37:50
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 11:21:15
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User closed query 'Please revise to nasal swab as it was collected on this date and should be in this CRF.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:05:11
DataPoint Verified.		12 Apr 2021 14:05:09
Query 'Please revise to nasal swab as it was collected on this date and should be in this CRF.' answered with 'UPDATED TO NASAL SWAB' (Site from CRA).	douglas winter (b) (4) (b) (4)	30 Mar 2021 21:02:56
User entered 'Nasal Swab (Nasal Swab)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Mar 2021 21:02:45
User opened query 'Please revise to nasal swab as it was collected on this date and should be in this CRF.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 18:25:59
Query 'Please revise to nasal swab.' canceled (Site from CRA).		17 Feb 2021 18:25:37
User opened query 'Please revise to nasal swab.' (Site from CRA).		17 Feb 2021 18:25:33
DataPoint Un-verified.		17 Feb 2021 18:25:19
DataPoint Verified.		17 Feb 2021 18:25:17
User entered 'Saliva Test (Saliva Test)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[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)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25



US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:25:17
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:25

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:05:02

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:22:54
User entered '0'	System	04 Jan 2021 12:57:26

US3222462

Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:05:02

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:30:16
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User closed query 'Please revise to No.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:05:30
DataPoint Verified.		12 Apr 2021 14:05:28
Query 'Please revise to No.' answered with 'corrected' (Site from CRA).		07 Apr 2021 13:28:50
User entered 'No (N)' reason for change: Data Entry Error		07 Apr 2021 13:28:43
User opened query 'Please revise to No.' (Site from CRA).		17 Feb 2021 18:25:12
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:57:33

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 3 (Day 3)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered '25 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 5 (Day 5)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered '27 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 7 (Day 7)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered '29 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 9 (Day 9)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered '31 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 23:18:50
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02



US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 14 (Day 14)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 21 (Day 21)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User accepted default value 'Day 28 (Day 28)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered 'NA (COVID-19 Negative) (NA)'	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02



US3222462

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:23:57
User entered empty.	douglas winter (b) (4) (b) (4)	09 Jan 2021 17:16:02

US3222462

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:34
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:06
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 25DEC2020, 27DEC2020 and 29DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).		17 Feb 2021 10:34:38
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 25DEC2020, 27DEC2020 and 29DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' answered with 'UPDATED SALIVA PAGE' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 23:20:12
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 25DEC2020, 27DEC2020 and 29DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 11:22:13
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:34
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:06
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:34
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:06
User entered 'Clinic (Clinic)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:34
User entered 'SICKD1'	System	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '10:16'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28



US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User entered '23 Dec 2020 10:16'	System	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '190.5' cm	douglas winter (b) (4)	23 Dec 2020 20:00:28
DataPoint set to visible.	(b) (4) System	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '132.2' kg	douglas winter (b) (4)	23 Dec 2020 20:00:28
DataPoint set to visible.	(b) (4) System	23 Dec 2020 19:59:24

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '36.7' C	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered 'Oral (Oral)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered empty.	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '53'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User entered 'bpm'	System	23 Dec 2020 20:00:28



US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '20'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User entered 'breaths/min'	System	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '131'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User entered 'mmHg'	System	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:26
User entered '80'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40
User entered 'mmHg'	System	23 Dec 2020 20:00:28

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40

US3222462

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:40



US3222462

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:49
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:38
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:40

US3222462

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:49
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:38
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:40

US3222462

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:02

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:55
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:45
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:51

US3222462

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:05:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:55
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:22:45
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		18 Jan 2021 11:08:37
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F60FBZ' (Site from DM).	douglas winter (b) (4) (b) (4)	11 Jan 2021 15:18:02
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:18:01
User entered '23 Dec 2020'	douglas winter (b) (4) (b) (4)	23 Dec 2020 20:00:51

US3222462

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:01:50
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:14:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 12:27:44
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 18:07:09

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:20:07
DataPoint Verified.		17 Feb 2021 18:15:42
User entered 'USA-US104-2021-mRNA-1273-P301000007'	System	03 Feb 2021 14:34:42
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 14:34:42

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event term 'bladder infection/urosepsis' contains multiple event terms. Please consider separating them into separate events. If not, please clarify. ' (Site from Safety). User closed query 'Source indicates this is Bladder infection/Urosepsis. Please confirm and revise if necessary.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 20:19:01
		12 Apr 2021 14:04:25
		12 Apr 2021 14:04:21
Query 'Source indicates this is Bladder infection/Urosepsis. Please confirm and revise if necessary.' answered with 'corrected' (Site from CRA).		07 Apr 2021 13:29:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Urosepsis, LLT: Urosepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:52:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Diana Toney (b) (4) (b) (4)	01 Mar 2021 20:52:55 21 Feb 2021 14:59:41 21 Feb 2021 14:58:45
User entered 'BLADDER INFECTION/ Urosepsis' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	21 Feb 2021 14:58:45
User opened query 'Source indicates this is Bladder infection/Urosepsis. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 18:16:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Bladder infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 12:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder User entered 'Bladder infection'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	02 Feb 2021 12:39:35 02 Feb 2021 12:38:24 02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:14:30
User entered 'Yes (Y)'		02 Feb 2021 12:37:51



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Urosepsis is not a solicited adverse reaction. Please confirm and revise here and in source.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:02:28
User closed query 'Per CDM: Was this a Solicited Adverse Reaction? is recorded as Yes, However this Indication is not listed in the Solicited Adverse Reactions as per CCG. Please review and update accordingly, else clarify.' (Site from DM).		08 Apr 2021 11:51:33
Query 'Per CDM: Was this a Solicited Adverse Reaction? is recorded as Yes, However this Indication is not listed in the Solicited Adverse Reactions as per CCG. Please review and update accordingly, else clarify.' answered with 'corrected' (Site from DM).		07 Apr 2021 13:33:33
Query 'Urosepsis is not a solicited adverse reaction. Please confirm and revise here and in source.' answered with 'corrected' (Site from CRA).		07 Apr 2021 13:33:24
User entered 'No (N)' reason for change: Data Entry Error		07 Apr 2021 13:33:16
User opened query 'Per CDM: Was this a Solicited Adverse Reaction? is recorded as Yes, However this Indication is not listed in the Solicited Adverse Reactions as per CCG. Please review and update accordingly, else clarify.' (Site from DM).		05 Mar 2021 13:53:08
User opened query 'Urosepsis is not a solicited adverse reaction. Please confirm and revise here and in source.' (Site from CRA).		17 Feb 2021 18:15:37
User entered 'Yes (Y)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:36
User entered 'No (N)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:25
User entered '25 Jan 2021'		02 Feb 2021 12:37:51

**US3222462**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:27
User entered empty.		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:27:16
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).		24 Apr 2021 15:13:12
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:22:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		09 Feb 2021 23:21:05
User entered empty.		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 12:37:51



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:27:19
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		09 Feb 2021 23:24:32
User entered empty.	System	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:39
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		02 Feb 2021 13:52:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:17:41
User entered 'Yes (Y)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:03
DataPoint Verified.		17 Feb 2021 18:17:44
User entered '0'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:04
DataPoint Verified.		17 Feb 2021 18:17:46
User entered '0'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered 'I'	System	02 Feb 2021 12:37:51
	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:26:36
User entered empty.		02 Feb 2021 12:37:51



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	02 Feb 2021 12:37:51
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:08
User entered 'Not Related (NOT RELATED)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:10
User entered 'Not Related (NOT RELATED)'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		02 Feb 2021 13:51:54
User entered 'None (NONE)'		02 Feb 2021 12:37:51



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:15
User entered '0' reason for change: Data Entry Error		02 Feb 2021 13:51:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 12:40:09
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 12:40:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 12:37:51
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:19
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).		09 Feb 2021 23:25:51
User entered '1' reason for change: Data Entry Error		02 Feb 2021 13:51:54
User entered '0'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:18:20
User entered '0'		02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Apr 2021 15:13:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Apr 2021 15:13:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Apr 2021 15:13:12
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 23:25:12
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 13:51:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 13:51:54
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 12:40:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 12:40:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 12:40:09
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 12:37:51
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'When conmeds for this AE become known, please enter these in conmed CRF and source.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 18:20:32
User entered 'PATIENT IS CURRENTLY ADMITTED WITH A BLADDER INFECTION. HAS BEEN HOSPITALIZED FOR THE PAST 9 DAYS. will request records after discharge.' reason for change: Data Entry Error		02 Feb 2021 13:51:54
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Feb 2021 12:40:09
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Feb 2021 12:40:09
User entered 'Patient is currently admitted with a bladder infection. Has been hospitalized for the past 9 days.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 12:40:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Feb 2021 12:37:51
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 12:37:51

US3222462

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:05:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 12:37:51

US3222462

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:05:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 12:37:51



US3222462

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 12:37:51

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:02

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:01:50
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:19:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	19 Oct 2020 12:22:35
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Oct 2020 14:34:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Oct 2020 14:34:02
User entered 'No (N)'	Albert Garcia (b) (4)	09 Oct 2020 18:07:02

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
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)	22 Oct 2020 17:57:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 17:57:45
Data point term sent to Coder	System	22 Oct 2020 17:56:21
User entered 'ASPIRIN'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'CARDIAC HEALTH'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '81'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'mg (mg)'	(b) (4) Albert Garcia (b) (4)	22 Oct 2020 17:56:04

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'as needed (PRN)'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '01 Jan 2018'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:56:04
	(b) (4)	



US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:19:18
Query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly.' answered with 'transcript error' (Site from DM).		12 Nov 2020 19:00:30
User entered 'No (N)' reason for change: Data Entry Error		12 Nov 2020 19:00:04
User opened query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly.' (Site from DM).		29 Oct 2020 13:45:09
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:56:04

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:56:04

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:56:04

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:56:04

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM HYDROCHLORIDE, PRODUCTSYNONYM: CARTIA XT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 08:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 08:53:34
Data point term sent to Coder	System	22 Oct 2020 17:59:26
User entered 'CARIA XT'	Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'ATRIAL FIBRILLATION'	(b) (4) Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '180'	(b) (4) Albert Garcia (b) (4)	22 Oct 2020 17:58:29



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:58:29

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:05:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Oral (ORAL)'	(b) (4) Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'I'	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	22 Oct 2020 17:58:29
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:58:29

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:58:29

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 12:19:33
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 Oct 2020 12:19:33
Data point term sent to Coder	System	24 Oct 2020 12:18:45
User entered 'LISINOPRIL'	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 12:18:01

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:05:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '20'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'once daily (QD)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'UN UNK 2014'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:01
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	24 Oct 2020 12:18:01

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 12:18:01

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 12:18:01

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 12:18:01



US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Oct 2020 12:19:33
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 Oct 2020 12:19:33
Data point term sent to Coder	System	24 Oct 2020 12:18:47
User entered 'METOPROLOL'	Albert Garcia (b) (4) (b) (4)	24 Oct 2020 12:18:32

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:05:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '50'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'once daily (QD)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'UN UNK 2015'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	24 Oct 2020 12:18:32
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 12:18:32



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 12:18:32

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 12:18:32

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User closed query 'Please enter this in con med source log' (Site from CRA).		28 Apr 2021 15:43:52
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Query 'Please enter this in con med source log' answered with 'updated' (Site from CRA).	(b) (4)	
	Diana Toney (b) (4)	21 Feb 2021 14:55:51
	(b) (4)	
User opened query 'Please enter this in con med source log' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 18:19:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 15:32:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 15:32:03
	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 15:31:35
Coding entries removed.	Jennifer Dittman (b) (4)	19 Nov 2020 15:30:52
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:48:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:48:42
	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 11:48:17
User entered 'INFLUENZA VACCINE'	Albert Garcia (b) (4)	28 Oct 2020 11:47:47
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 18:19:23
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 18:19:21
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4)	
reason for change: Data Entry Error	Jennifer Dittman (b) (4)	19 Nov 2020 15:30:52
User entered 'INFLUENZA'	(b) (4)	
	Albert Garcia (b) (4)	28 Oct 2020 11:47:47
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Jennifer Dittman (b) (4)	19 Nov 2020 15:30:52
User entered '1'	(b) (4)	
	Albert Garcia (b) (4)	28 Oct 2020 11:47:47
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Dittman (b) (4)	19 Nov 2020 15:30:52
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	28 Oct 2020 11:47:47
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:47:47



US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'once (ONCE)'	(b) (4) Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '21 Oct 2020'	Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '21 Oct 2020'	Albert Garcia (b) (4)	28 Oct 2020 11:47:47



US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:05:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	28 Oct 2020 11:47:47

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User entered empty.	System	28 Oct 2020 11:47:47

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User entered empty.	System	28 Oct 2020 11:47:47

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:21
User entered empty.	System	28 Oct 2020 11:47:47

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 11:41:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 11:41:16
Data point term sent to Coder Coding entries removed.	System Alicia Cevera (b) (4)	29 Jan 2021 11:40:24 29 Jan 2021 11:39:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:00:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:00:21
Data point term sent to Coder User entered 'IBUPROFEN'	System Albert Garcia (b) (4)	28 Oct 2020 11:52:19 28 Oct 2020 11:51:51

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:05:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:36:09
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated con med and med hx page' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	29 Jan 2021 11:40:09
User entered 'generalized muscle pain' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	29 Jan 2021 11:39:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:03:31
User entered 'PAIN, UNKNOWN'	Albert Garcia (b) (4) (b) (4)	28 Oct 2020 11:51:51

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '200'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'as needed (PRN)'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '01 Jan 2005'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	28 Oct 2020 11:51:51
	(b) (4)	

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	28 Oct 2020 11:51:51

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 11:51:51

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 11:51:51

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 11:51:51

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Nov 2020 19:25:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 19:25:45
Data point term sent to Coder	System	12 Nov 2020 19:24:58
User entered 'ibuprofen'	(b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57



US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:36:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' answered with 'does not meet AE criteria solicited adverse reaction' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	29 Jan 2021 11:42:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:04:02

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Indication](#)

Audit	User	Time (GMT)
User entered 'fever'	(b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '400' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 19:33:31
User entered '500'	(b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:05:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 19:24:57



US3222462

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:05:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 19:24:57

US3222462

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:05:02**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	09 Oct 2020 18:06:57
	(b) (4)	

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'USA-US104-2021-MRNA-1273-P301000007'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Bruce'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Teresa'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Rankin'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Becker'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '860 Peachwood Ave'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '6550 Mapleridge Street'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Deland'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Houston'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '32720'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '77081'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'US'	System	03 Feb 2021 14:34:56



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:52:31
User entered '1'	System	03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'USA-US104-2021-MRNA-1273-P301000007'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Bruce'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Teresa'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Rankin'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Becker'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '860 Peachwood Ave'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '6550 Mapleridge Street'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Deland'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Houston'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '32720'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '77081'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'US'	System	03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:52:31
User entered '1'	System	03 Feb 2021 14:34:56



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '03/Feb/2021 09:34'	(b) (4) System	03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:02

**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.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'I'		03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'USA-US104-2021-MRNA-1273-P301000007'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Bruce'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Teresa'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Rankin'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Becker'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '860 Peachwood Ave'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '6550 Mapleridge Street'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Deland'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Houston'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '32720'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '77081'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'US'	System	03 Feb 2021 14:34:56



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:52:31
User entered '1'	System	03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
User entered '22/Feb/2021 12:52'	(b) (4) System	22 Feb 2021 17:52:31

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:02

**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.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:52:58
User entered 'I'		22 Feb 2021 17:52:31

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'USA-US104-2021-MRNA-1273-P301000007'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:34:42



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'No (N)'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Bruce'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Teresa'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Rankin'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Becker'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '860 Peachwood Ave'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '6550 Mapleridge Street'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered 'Deland'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'Houston'	System	03 Feb 2021 14:34:42

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
	(b) (4)	
Un-reviewed for Safety.	System	26 Apr 2021 14:20:23
Signature has been broken.	System	26 Apr 2021 14:20:23
User entered '32720'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered '77081'	System	03 Feb 2021 14:34:42



US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:35:00
User entered 'US'	System	03 Feb 2021 14:34:56

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 14:20:23
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:39:17
	(b) (4)	
User entered '2'	System	22 Feb 2021 17:52:31
User entered '1'	System	03 Feb 2021 14:34:56

**US3222462**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:05:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered '26/Apr/2021 09:20'	(b) (4) System	26 Apr 2021 14:20:23

US3222462

Folder: SAE USA-US104-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:02

**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.	Bruce Rankin (b) (4)	26 Apr 2021 14:35:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:20:23