

US3362071 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:14:15

All time stamps listed in this document are displayed in GMT

US3362071

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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[Participant ID](#)

US3362071

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

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US3362071

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362071

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
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) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Date of Informed Consent (*dd MMM yyyy*) 07 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3362071

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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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) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	NON-STEMI MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1978
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	PHEOCHROMOCYTOMA
Start date (dd MMM yyyy)	14 JUN 2016
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)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	SYSTOLIC CHF
Start date (dd MMM yyyy)	14 JUN 2016
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)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	PULMONARY HYPERTENSION
Start date (dd MMM yyyy)	14 JUN 2016
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)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	14 JUN 2016
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)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	14 JUL 2016
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)	JUL 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:07 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:07
Height ( <i>xxx.x</i> )	181 cm
Weight ( <i>xxx.x</i> )	140 kg
BMI ( <i>xxx.x</i> )	42.73374 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) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:14:49

Generated On: 09 Jun 2021 17:14:15

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:14:49

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143268

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Height	ND - Not Done
Weight	ND - Not Done

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

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)	07 AUG 2020
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 09:07
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

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)	07 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3362071

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 10:21

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 AUG 2020

Collection time (00:00-23:59)

09:47 (24 HR)

Collection date and time (derived)

07 AUG 2020 09:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:45	07 AUG 2020 09:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 10:42

PC Open Date & Time

07 AUG 2020 10:41

PC Close Date & Time

07 AUG 2020 13:11

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	07 AUG 2020 14:07
PC Open Date & Time	07 AUG 2020 14:06
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 04:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 12:22

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**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

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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

07 AUG 2020 10:41

PC Open Date & Time

07 AUG 2020 10:41

PC Close Date & Time

07 AUG 2020 13:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**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

07 AUG 2020 14:11

PC Open Date & Time

07 AUG 2020 14:06

PC Close Date & Time

08 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**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

08 AUG 2020 12:15

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**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

10 AUG 2020 04:03

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**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

10 AUG 2020 12:22

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**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

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**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

12 AUG 2020 13:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**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

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 10:42
PC Open Date & Time	07 AUG 2020 10:41
PC Close Date & Time	07 AUG 2020 13:11

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 14:11
PC Open Date & Time	07 AUG 2020 14:06
PC Close Date & Time	08 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**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 ☒

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:15
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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)

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 04:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

57 of 3190

EAB) (1725)

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 12:23
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

59 of 3190

EAB) (1725)

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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 ☒

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:21
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**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

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EAB) (1725)

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

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)	4 SEP 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 08:40
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

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)	4 SEP 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 10:01
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3362071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 09:20 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 09:20

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

US3362071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	08:57 (24 HR)
Collection date and time (derived)	4 SEP 2020 08:57

US3362071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:49	4 SEP 2020 08:49
Nasopharyngeal Swab 2	No		

US3362071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 10:00

PC Open Date & Time

04 SEP 2020 09:40

PC Close Date & Time

04 SEP 2020 12:10

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**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 98.2 °F

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

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

PC Time Stamp	04 SEP 2020 20:07
PC Open Date & Time	04 SEP 2020 13:05
PC Close Date & Time	05 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °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 14:42
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**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.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 6

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

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

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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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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

04 SEP 2020 10:00

PC Open Date & Time

04 SEP 2020 09:40

PC Close Date & Time

04 SEP 2020 12:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**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

04 SEP 2020 20:09

PC Open Date & Time

04 SEP 2020 13:05

PC Close Date & Time

05 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**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

05 SEP 2020 14:43

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

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 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

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

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 10:01
PC Open Date & Time	04 SEP 2020 09:40
PC Close Date & Time	04 SEP 2020 12:10

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**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 ☐

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:08
PC Open Date & Time	04 SEP 2020 13:05
PC Close Date & Time	05 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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 ☒

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 14:43
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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 ☐

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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 ☐

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3362071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:19

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:38
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3362071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	08:54 (24 HR)
Collection date and time (derived)	29 SEP 2020 08:54

US3362071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:29:20

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 OCT 2020 15:06:49
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 13:13:08

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 12:59:15
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 05:46:32
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 07:43:51
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 05:05:56

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 08:12:33
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	01 DEC 2020 13:21:12
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2020 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

13 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59
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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 05:26:04

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 08:00:29
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	17 JAN 2021 09:04:24
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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

24 JAN 2021 05:11:34

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 02:48:07
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 09:03:45
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 02:47:02
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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 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	21 FEB 2021 03:13:41
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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

28 FEB 2021 04:24:41

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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 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	11 MAR 2021 07:30:15
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 04:10:08
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 03:44:07

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 10:58:52
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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

05 APR 2021 12:50:16

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 11:25:21
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 19:54:13

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 09:02:29

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 04:44:38
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 292

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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°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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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°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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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="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"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**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°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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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 ☐

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59

US3362071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

US3362071

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:14:15

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		28 FEB 2021 04:24:28

US3362071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:17:39

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:17:38

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

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

Visit date (dd MMM yyyy)	26 FEB 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3362071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

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) \_\_\_\_\_

US3362071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

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.*

US3362071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 FEB 2021

Collection time (00:00-23:59)

09:09 (24 HR)

Collection date and time (derived)

26 FEB 2021 09:09

US3362071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3362071

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:05:13

Generated On: 09 Jun 2021 17:14:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3362071**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

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*

**US3362071**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Date of Contact	07 DEC 2020
Time of Contact	13:24
Date and Time of Contact (derived)	07 DEC 2020 13:24
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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"/>

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

Date	23 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	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 (2)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 (2)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (3)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

Date	26 NOV 2020
------	-------------

Assessment Not Done	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (6)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	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 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

Date	29 NOV 2020
------	-------------

Assessment Not Done	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 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 (7)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 (8)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (9)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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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Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

Date	01 DEC 2020
------	-------------

Assessment Not Done	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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 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 (10)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

Date	03 DEC 2020
------	-------------

Assessment Not Done	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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EAB) (1725)

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Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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	04 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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	05 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 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 (13)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (14)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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	06 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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EAB) (1725)

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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 (14)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (15)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (15)

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Generated On: 09 Jun 2021 17:14:15

	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	07 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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	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 (15)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (16)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input 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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Form: Symptom Log (16)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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	08 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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	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 (16)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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 (17)

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Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	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	09 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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	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 (17)

Data signed: (b) (4) 24 Apr 2021 00:05:11

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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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Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	36.7 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 07 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

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Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Symptom Day

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

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

Date of Visit 10 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 10 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

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:05:11

Generated On: 09 Jun 2021 17:14:15

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	14 DEC 2020
Day 7	No	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3362071

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	10:13 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 10:13
Height ( <i>xxx.x</i> )	181 cm
Weight ( <i>xxx.x</i> )	140 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> )	107 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362071

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3362071

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020

US3362071

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

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

Visit date (dd MMM yyyy)	26 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3362071

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Date of updated informed consent (dd MMM yyyy) 26 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 26 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3362071

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 FEB 2021

Collection time (00:00-23:59)

09:09 (24 HR)

Collection date and time (derived)

26 FEB 2021 09:09

US3362071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:05:12

Generated On: 09 Jun 2021 17:14:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 FEB 2021
Collection time (00:00 - 23:59)	09:13
Collection Date and Time (derived)	26 FEB 2021 09:13

US3362071

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:10:55

Generated On: 09 Jun 2021 17:14:15

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3362071

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	USA-US112-2020-MRNA-1273-P30 1000013
Adverse event	UPPER RESPIRATORY INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
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)	03 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	5 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3362071

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

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SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS ADMITTED INTO OSCHNER HOSPITAL; WILL REQUEST MEDICAL RECORDS. MEDICAL RECORDS REVEAL COVID-19 RESULTS WERE NEGATIVE.

---

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

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US3362071

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	USA-US112-2020-MRNA-1273-P30 1000013
Adverse event	DEHYDRATION
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)	3 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 DEC 2020
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)	3 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	5 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS ADMITTED WITH THE ABOVE DX. THEN ON 05DEC2020 DISCHARGED TO HOME.
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: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	USA-US112-2020-MRNA-1273-P30 1000013
Adverse event	SHORTNESS OF BREATH
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)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 DEC 2020
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)	3 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	5 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS ADMITTED FOR COVID LIKE SYMTOMS
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

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	USA-US112-2020-MRNA-1273-P30 1000013
Adverse event	ABDOMINAL PAIN
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)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 DEC 2020
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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	5 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

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SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS ADMITTED INTO OSCHNER HOSPITAL; THIS IS AN OVERLAPPING SAE WITH SOB AND UPPER RESPIRATORY INFECTION. HOSPITAL RECORDS WERE ALREADY SENT. STILL AWAITING URGENT CARE RECORDS. MEDICAL RECORDS REVEAL COVID-19 RESULTS WERE NEGATIVE.

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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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US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	
Adverse event	GASTROESOPHAGEAL REFLUX DIESEASE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	03 DEC 2020
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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

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

US3362071

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

AEID	USA-US112-2021-MRNA-1273-P30 1000013
Adverse event	DISSECTING AORTA
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)	5 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 MAR 2021
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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	10 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3362071

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 00:06:54

Generated On: 09 Jun 2021 17:14:15

---

SUBJECT CONTACTED SITE TO  
NOTIFY OF HOSPITAL  
ADMISSION ON 05MAR2021 FOR  
ABDOMINAL PAIN, DX WITH  
DISSECTING AORTA, MEDICAL  
MANGEMENT WITH ORAL  
MEDICATION, NO SURGERY,  
INSTRUCTED TO FOLLOW UP  
WITH VASCULAR SPECIALIST  
AFTER DISCHARGE, RECORDS  
REQUESTED.

---

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

---

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:48:29

Generated On: 09 Jun 2021 17:14:15

---

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

Yes ☒

No ☐

---

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

---

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication HYPERLIPIDEMIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐  
No ☒

Indication PRINCIPAL AE:DEHYDRATION

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPORT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication AMOXICILLIN CLAVULUNATE

Prophylaxis Yes ☐  
No ☒

Indication AE UPPER RESPIRATORY INFECTION

Dose per administration 500/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication DICYCLOMINE

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication PROTONIX

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication DISSECTING AORTA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication DISSECTING AORTA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication HISTORY OF NON-STEMI  
MYOCARDIAL INFARCT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:48:28

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

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication SYSTOLIC CONGESTIVE HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
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"/>

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication BENTYL

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

Name of Medication ALBUTEROL HFA

Prophylaxis Yes ☐  
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:48:28

Generated On: 09 Jun 2021 17:14:15

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:48:29

Generated On: 09 Jun 2021 17:14:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:48:29

Generated On: 09 Jun 2021 17:14:15

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
3 DEC 2020	COLONOSCOPY	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:15

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:15

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 ☐

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/DEC/2020 17:18
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	14/DEC/2020 12:54
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/DEC/2020 14:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	17/DEC/2020 10:08
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	22/DEC/2020 13:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	04/JAN/2021 19:05
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	13/JAN/2021 11:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/JAN/2021 07:34
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (9)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	25/MAR/2021 12:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (10)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	26/MAR/2021 08:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (11)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/APR/2021 14:18
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

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (12)

Data signed: (b) (4) 01 May 2021 03:16:11

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2020-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	30/APR/2021 12:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 03:16:12

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2021-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 03:16:12

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2021-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/MAR/2021 18:55
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

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 03:16:12

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2021-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:59
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

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 03:16:12

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2021-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/APR/2021 08:16
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

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 03:16:12

Generated On: 09 Jun 2021 17:14:15

SAEID	USA-US112-2021-MRNA-1273-P301000013
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	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/APR/2021 12:58
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

US3362071 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

**US3362071**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:14:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'US3362071'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 14:49:39

**US3362071**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:21:56
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 15:34:17

**US3362071**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:21:56
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 14:49:39

US3362071

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:21:56
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	07 Aug 2020 15:34:17

**US3362071**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'SCRN'	System	07 Aug 2020 15:34:17

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 14:49:40

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '52'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'YEARS'	System	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '52'	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered 'Male (M)'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

US3362071

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered 'l'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:14:15**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:23:11
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:28

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered '07 Aug 2020'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Aug 2020'	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2020'	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered 'Amendment 1 (1)'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 17:38:12
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:08

US3362071

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:24:04
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	12 Aug 2020 17:38:12
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	07 Aug 2020 15:35:08
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 14:49:39

**US3362071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:14:15**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'I'	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:14:15**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:09
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 15:34:27

**US3362071**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:14:15**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:24:13
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 11:13:50

US3362071

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
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)	08 Aug 2020 11:15:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 11:15:52
Data point term sent to Coder	System	08 Aug 2020 11:15:17
User entered 'Hypertension'	Crystal Rowell (b) (4) (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2015'	Crystal Rowell (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Crystal Rowell (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2015'	System	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2015'	System	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	08 Aug 2020 11:14:20

**US3362071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	08 Aug 2020 11:14:20

US3362071

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:40:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:40:18
Data point term sent to Coder	System	08 Aug 2020 11:15:18
User entered 'Non-STEMI Myocardial Infarcation'	Crystal Rowell (b) (4) (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2015'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'No (N)'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2015'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2015'	System	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2015'	System	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2015'	System	08 Aug 2020 11:15:11

**US3362071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2015'	System	08 Aug 2020 11:15:11

US3362071

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 11:17:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 11:17:38
Data point term sent to Coder	System	08 Aug 2020 11:16:18
User entered 'Appendectomy'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 1978'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'No (N)'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 1978'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 1978'	System	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '1978'	System	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 1978'	System	08 Aug 2020 11:15:48

**US3362071**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '1978'	System	08 Aug 2020 11:15:48

US3362071

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 15:35:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'history of colon cancer in family ; diagnostic' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:18:42
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:26:13
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 11:17:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 11:17:38
Data point term sent to Coder	System	08 Aug 2020 11:16:18
User entered 'Colonoscopy'	Crystal Rowell (b) (4) (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2000'	Crystal Rowell (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'No (N)'	Crystal Rowell (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2000'	Crystal Rowell (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Crystal Rowell (b) (4)	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2000'	System	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2000'	System	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2000'	System	08 Aug 2020 11:16:17

**US3362071**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2000'	System	08 Aug 2020 11:16:17

US3362071

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:48:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 18:48:00
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 18:46:35
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'un UNK 2015'	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jan 2015'	System	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2015'	System	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	25 Sep 2020 18:45:52

**US3362071**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	25 Sep 2020 18:45:52

US3362071

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Islet cell neoplasms and APUDoma NEC, PT: Pheochromocytoma, LLT: Pheochromocytoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:10:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:10:54
Data point term sent to Coder	System	16 Mar 2021 20:09:34
User entered 'Pheochromocytoma'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '14 Jun 2016'	Alexandra Caillouet	16 Mar 2021 20:09:04
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:09:04
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:09:04
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jun 2016'	System	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2016'	System	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:04

**US3362071**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:04

US3362071

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Congestive cardiomyopathy, LLT: Dilated cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 20:25:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 20:25:59
Data point term sent to Coder	System	16 Mar 2021 20:09:34
User entered 'Dilated Cardiomyopathy'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet	16 Mar 2021 20:09:31
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'I'	Alexandra Caillouet	16 Mar 2021 20:09:31
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet (b) (4)	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:09:31
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:31

**US3362071**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:09:31

US3362071

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:26:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:26:33
Data point term sent to Coder	System	16 Mar 2021 20:10:39
User entered 'Systolic CHF'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:05

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '14 Jun 2016'	Alexandra Caillouet	16 Mar 2021 20:10:05
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:10:05
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:05

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet	16 Mar 2021 20:10:05
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:10:05
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jun 2016'	System	16 Mar 2021 20:10:05

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2016'	System	16 Mar 2021 20:10:05

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:10:05

**US3362071**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:10:05

US3362071

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary hypertension, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:11:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:11:55
Data point term sent to Coder	System	16 Mar 2021 20:10:37
User entered 'Pulmonary Hypertension'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '14 Jun 2016' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:50
User entered '14 Jun 2020'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:10:29
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet	16 Mar 2021 20:10:29
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:10:29
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jun 2016'	System	16 Mar 2021 20:10:50
User entered 'Jun 2020'	System	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2016'	System	16 Mar 2021 20:10:50
User entered '2020'	System	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:10:29

**US3362071**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:10:29

US3362071

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:13:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:13:59
Data point term sent to Coder	System	16 Mar 2021 20:12:55
User entered 'Chronic Kidney Disease'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:12:27

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '14 Jun 2016'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:12:27

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:12:27
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet	16 Mar 2021 20:12:27
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet	16 Mar 2021 20:12:27
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:12:27
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jun 2016'	System	16 Mar 2021 20:12:27

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2016'	System	16 Mar 2021 20:12:27

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:12:27

**US3362071**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:12:27

US3362071

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:25:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:59:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 20:59:55
Data point term sent to Coder	System	16 Mar 2021 20:58:55
User entered 'Obstructive Sleep Apnea'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '14 Jul 2016'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered empty.	Alexandra Caillouet	16 Mar 2021 20:58:49
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:25:53
User entered '0'	Alexandra Caillouet	16 Mar 2021 20:58:49
	(b) (4)	

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'Jul 2016'	System	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '2016'	System	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered empty.	System	16 Mar 2021 20:58:49

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

US3362071

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

US3362071

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:27:21
User closed query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	26 Aug 2020 18:50:18
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	26 Aug 2020 18:50:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 18:50:18
User opened query 'Response to were vital signs assessed is No, but height or weight is provided. Please correct.' (Site from System).	System	26 Aug 2020 18:50:09
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	26 Aug 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered '07 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:27:21
User closed query 'Per CDM: Please confirm if time 09:07 is AM or PM. Thank you!' (Site from DM).		25 Sep 2020 08:35:24
Query 'Per CDM: Please confirm if time 09:07 is AM or PM. Thank you!' answered with 'per 24 hour time clock, 0907 is AM' (Site from DM).		24 Sep 2020 17:24:01
User opened query 'Per CDM: Please confirm if time 09:07 is AM or PM. Thank you!' (Site from DM).		24 Sep 2020 10:34:53
User entered '09:07'		26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered '07 Aug 2020 09:07'	System	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered '181' cm	(b) (4), (b) (6)	26 Aug 2020 18:50:09
DataPoint set to visible.	System	07 Aug 2020 15:35:08

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered '140' kg	(b) (4), (b) (6)	26 Aug 2020 18:50:09
DataPoint set to visible.	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
Amendment Manager: User entered '42.73374'	System	16 Sep 2020 23:47:07
User entered '42.7'	System	26 Aug 2020 18:50:09
DataPoint set to visible.	System	07 Aug 2020 15:35:08

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'kg/m2'	System	26 Aug 2020 18:50:09
DataPoint set to visible.	System	07 Aug 2020 15:35:08

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:35:26
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:24:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:24:26
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:34:37
User entered '36.8' C	(b) (4), (b) (6)	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered empty; reason for change Data Entry Error		24 Sep 2020 17:24:26
User entered 'Oral (Oral)'		26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error		24 Sep 2020 17:24:26
User entered '83'		26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'bpm'	System	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:24:26
User entered '16'	(b) (4), (b) (6)	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'breaths/min'	System	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:24:26
User entered '122'	(b) (4), (b) (6)	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'mmHg'	System	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 17:24:26
User entered '75'	(b) (4), (b) (6)	26 Aug 2020 18:50:09

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User entered 'mmHg'	System	26 Aug 2020 18:50:09

**US3362071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

US3362071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28

**US3362071**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:50:34

US3362071

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:27
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 13:09:47
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 15:45:41
User entered '07 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:50:34

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

**US3362071**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:14:15**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:52:48

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

**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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

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 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered 'l'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:21:28
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:14:50
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:27:33
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:52:48

US3362071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:54:09

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:54:09

US3362071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:54:09

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'VISIT1'	System	26 Aug 2020 18:54:09

US3362071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:04:30

US3362071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:49:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:49:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 15:04:30
User entered '143268' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:04:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 15:04:30

US3362071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

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)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:16:54

US3362071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

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)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:16:54

US3362071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:16:54

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:14:15**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:16:54

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:14:15**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:16:54

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:35:12
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:34:27
User entered '181' cm	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User entered '140' kg	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:35:12
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:34:27
User entered '181' cm	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User entered '140' kg	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '09:07'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '07 Aug 2020 09:07'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '83'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'bpm'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'breaths/min'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '122'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '75'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 08:35:12
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:34:27
User entered '181' cm	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:18:29
User entered '140' kg	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '11:05'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '07 Aug 2020 11:05'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '80'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'bpm'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'breaths/min'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '125'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '77'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	26 Aug 2020 19:29:58

US3362071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:45:18

US3362071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:45:18

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '10:21'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '07 Aug 2020 10:21'	System	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Right Arm (RIGHT ARM)'	Crystal Rowell (b) (4)	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'ONCE'	System	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 15:35:46

US3362071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:01

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:01

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '09:47'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:01

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '07 Aug 2020 09:47'	System	26 Aug 2020 19:46:01

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:14:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Aug 2020 19:46:56

US3362071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '09:45'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '07 Aug 2020 09:45'	System	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Aug 2020 19:46:56

US3362071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:46:56

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered empty.	System	26 Aug 2020 19:46:56

US3362071

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:14:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 19:47:20

**US3362071**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	26 Aug 2020 19:47:20

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88470de3-355a-490d-bf5f-86940e349cd2'	System	07 Aug 2020 15:42:09
User entered 'Yes (Y)'	System	07 Aug 2020 15:42:09

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88470de3-355a-490d-bf5f-86940e349cd2'	System	07 Aug 2020 15:42:09
User entered '98.6'	System	07 Aug 2020 15:42:09

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:01', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88470de3-355a-490d-bf5f-86940e349cd2'	System	07 Aug 2020 15:42:09
User entered 'No (N)'	System	07 Aug 2020 15:42:09

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:05', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88470de3-355a-490d-bf5f-86940e349cd2'	System	07 Aug 2020 15:42:09
User entered '07 Aug 2020 10:42'	System	07 Aug 2020 15:42:09

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 10:41'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:07:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '61db5efb-2b57-4867-bdf7-347d0aad6039'	System	07 Aug 2020 19:07:37
User entered 'Yes (Y)'	System	07 Aug 2020 19:07:37

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:07:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '61db5efb-2b57-4867-bdf7-347d0aad6039'	System	07 Aug 2020 19:07:37
User entered '98.0'	System	07 Aug 2020 19:07:37

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:07:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '61db5efb-2b57-4867-bdf7-347d0aad6039'	System	07 Aug 2020 19:07:37
User entered 'No (N)'	System	07 Aug 2020 19:07:37

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:07:35', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '61db5efb-2b57-4867-bdf7-347d0aad6039'	System	07 Aug 2020 19:07:37
User entered '07 Aug 2020 14:07'	System	07 Aug 2020 19:07:37

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 14:06'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 2'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:31', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '802d2b48-098f-4095-8233-b6af477a60e1'	System	08 Aug 2020 17:14:53
User entered 'Yes (Y)'	System	08 Aug 2020 17:14:53

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:37', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '802d2b48-098f-4095-8233-b6af477a60e1'	System	08 Aug 2020 17:14:53
User entered '98.0'	System	08 Aug 2020 17:14:53

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '802d2b48-098f-4095-8233-b6af477a60e1'	System	08 Aug 2020 17:14:53
User entered 'No (N)'	System	08 Aug 2020 17:14:53

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:46', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '802d2b48-098f-4095-8233-b6af477a60e1'	System	08 Aug 2020 17:14:53
User entered '08 Aug 2020 12:14'	System	08 Aug 2020 17:14:53

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 3'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:27', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '24c0dfa5-9b05-433d-ba17-c9854296e94b'	System	10 Aug 2020 09:02:47
User entered 'Yes (Y)'	System	10 Aug 2020 09:02:47

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:37', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '24c0dfa5-9b05-433d-ba17-c9854296e94b' User entered '98.0'	System	10 Aug 2020 09:02:47
	System	10 Aug 2020 09:02:47

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '24c0dfa5-9b05-433d-ba17-c9854296e94b'	System	10 Aug 2020 09:02:47
User entered 'No (N)'	System	10 Aug 2020 09:02:47

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:44', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '24c0dfa5-9b05-433d-ba17-c9854296e94b'	System	10 Aug 2020 09:02:47
User entered '10 Aug 2020 04:02'	System	10 Aug 2020 09:02:47

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 4'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:16', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '14179f3d-0bde-470f-9728-cb538ecf9f32'	System	10 Aug 2020 17:22:33
User entered 'Yes (Y)'	System	10 Aug 2020 17:22:33

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:22', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '14179f3d-0bde-470f-9728-cb538ecf9f32'	System	10 Aug 2020 17:22:33
User entered '98.0'	System	10 Aug 2020 17:22:33

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:26', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '14179f3d-0bde-470f-9728-cb538ecf9f32'	System	10 Aug 2020 17:22:33
User entered 'No (N)'	System	10 Aug 2020 17:22:33

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '14179f3d-0bde-470f-9728-cb538ecf9f32'	System	10 Aug 2020 17:22:33
User entered '10 Aug 2020 12:22'	System	10 Aug 2020 17:22:33

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 5'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:19', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a49cad03-9f93-47cc-a6e7-78a8aa814854'	System	11 Aug 2020 17:01:39
User entered 'Yes (Y)'	System	11 Aug 2020 17:01:39

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:25', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a49cad03-9f93-47cc-a6e7-78a8aa814854'	System	11 Aug 2020 17:01:39
User entered '98.0'	System	11 Aug 2020 17:01:39

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a49cad03-9f93-47cc-a6e7-78a8aa814854'	System	11 Aug 2020 17:01:39
User entered 'No (N)'	System	11 Aug 2020 17:01:39

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:33', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a49cad03-9f93-47cc-a6e7-78a8aa814854'	System	11 Aug 2020 17:01:39
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:39

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 6'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:20:39', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '321cfe29-dcd9-4d22-a1bf-24c3a76d0121'	System	12 Aug 2020 18:21:06
User entered 'Yes (Y)'	System	12 Aug 2020 18:21:06

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:20:45', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '321cfe29-dcd9-4d22-a1bf-24c3a76d0121'	System	12 Aug 2020 18:21:06
User entered '98.0'	System	12 Aug 2020 18:21:06

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:20:57', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '321cfe29-dcd9-4d22-a1bf-24c3a76d0121'	System	12 Aug 2020 18:21:06
User entered 'No (N)'	System	12 Aug 2020 18:21:06

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '321cfe29-dcd9-4d22-a1bf-24c3a76d0121'	System	12 Aug 2020 18:21:06
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 18:21:06

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 7'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:18', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '50a26c4d-3c1a-465a-a9aa-d868b4bc670d'	System	07 Aug 2020 15:41:37
User entered 'None (1)'	System	07 Aug 2020 15:41:37

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '50a26c4d-3c1a-465a-a9aa-d868b4bc670d'	System	07 Aug 2020 15:41:37
User entered 'No (N)'	System	07 Aug 2020 15:41:37

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:25', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '50a26c4d-3c1a-465a-a9aa-d868b4bc670d'	System	07 Aug 2020 15:41:37
User entered 'No (N)'	System	07 Aug 2020 15:41:37

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '50a26c4d-3c1a-465a-a9aa-d868b4bc670d'	System	07 Aug 2020 15:41:37
User entered 'None (1)'	System	07 Aug 2020 15:41:37

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:41:33', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '50a26c4d-3c1a-465a-a9aa-d868b4bc670d'	System	07 Aug 2020 15:41:37
User entered '07 Aug 2020 10:41'	System	07 Aug 2020 15:41:37

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 10:41'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:10:19', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '98435168-3a77-4c80-86aa-1961752ff338'	System	07 Aug 2020 19:11:04
User entered 'None (1)'	System	07 Aug 2020 19:11:04

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:10:23', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '98435168-3a77-4c80-86aa-1961752ff338'	System	07 Aug 2020 19:11:04
User entered 'No (N)'	System	07 Aug 2020 19:11:04

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:10:46', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '98435168-3a77-4c80-86aa-1961752ff338'	System	07 Aug 2020 19:11:04
User entered 'No (N)'	System	07 Aug 2020 19:11:04

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:10:55', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '98435168-3a77-4c80-86aa-1961752ff338'	System	07 Aug 2020 19:11:04
User entered 'None (1)'	System	07 Aug 2020 19:11:04

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '98435168-3a77-4c80-86aa-1961752ff338'	System	07 Aug 2020 19:11:04
User entered '07 Aug 2020 14:11'	System	07 Aug 2020 19:11:04

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 14:06'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 2'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:55', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '3f07382f-e4b2-4cb1-a2e2-eca362e9f5ae'	System	08 Aug 2020 17:15:11
User entered 'None (1)'	System	08 Aug 2020 17:15:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:14:59', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '3f07382f-e4b2-4cb1-a2e2-eca362e9f5ae'	System	08 Aug 2020 17:15:11
User entered 'No (N)'	System	08 Aug 2020 17:15:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:01', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '3f07382f-e4b2-4cb1-a2e2-eca362e9f5ae'	System	08 Aug 2020 17:15:11
User entered 'No (N)'	System	08 Aug 2020 17:15:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '3f07382f-e4b2-4cb1-a2e2-eca362e9f5ae'	System	08 Aug 2020 17:15:11
User entered 'None (1)'	System	08 Aug 2020 17:15:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:07', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '3f07382f-e4b2-4cb1-a2e2-eca362e9f5ae'	System	08 Aug 2020 17:15:11
User entered '08 Aug 2020 12:15'	System	08 Aug 2020 17:15:11

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 3'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:49', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'fc469912-27b1-4c0a-9d60-c68219f558ba'	System	10 Aug 2020 09:03:09
User entered 'None (1)'	System	10 Aug 2020 09:03:09

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:53', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'fc469912-27b1-4c0a-9d60-c68219f558ba'	System	10 Aug 2020 09:03:09
User entered 'No (N)'	System	10 Aug 2020 09:03:09

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:02:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'fc469912-27b1-4c0a-9d60-c68219f558ba'	System	10 Aug 2020 09:03:09
User entered 'No (N)'	System	10 Aug 2020 09:03:09

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:01', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'fc469912-27b1-4c0a-9d60-c68219f558ba'	System	10 Aug 2020 09:03:09
User entered 'None (1)'	System	10 Aug 2020 09:03:09

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'fc469912-27b1-4c0a-9d60-c68219f558ba'	System	10 Aug 2020 09:03:09
User entered '10 Aug 2020 04:03'	System	10 Aug 2020 09:03:09

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 4'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:34', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1dafd463-517b-4d18-a9e4-b8dd6b6e0515'	System	10 Aug 2020 17:22:58
User entered 'None (1)'	System	10 Aug 2020 17:22:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:46', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1dafd463-517b-4d18-a9e4-b8dd6b6e0515'	System	10 Aug 2020 17:22:58
User entered 'No (N)'	System	10 Aug 2020 17:22:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:48', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1dafd463-517b-4d18-a9e4-b8dd6b6e0515'	System	10 Aug 2020 17:22:58
User entered 'No (N)'	System	10 Aug 2020 17:22:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:52', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1dafd463-517b-4d18-a9e4-b8dd6b6e0515'	System	10 Aug 2020 17:22:58
User entered 'None (1)'	System	10 Aug 2020 17:22:58

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:55', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1dafd463-517b-4d18-a9e4-b8dd6b6e0515'	System	10 Aug 2020 17:22:58
User entered '10 Aug 2020 12:22'	System	10 Aug 2020 17:22:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 5'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:38', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2f9fa674-7981-4f6e-a8d0-d71dbdd4ab14'	System	11 Aug 2020 17:01:58
User entered 'None (1)'	System	11 Aug 2020 17:01:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2f9fa674-7981-4f6e-a8d0-d71dbdd4ab14'	System	11 Aug 2020 17:01:58
User entered 'No (N)'	System	11 Aug 2020 17:01:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:44', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2f9fa674-7981-4f6e-a8d0-d71dbdd4ab14'	System	11 Aug 2020 17:01:58
User entered 'No (N)'	System	11 Aug 2020 17:01:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:48', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2f9fa674-7981-4f6e-a8d0-d71dbdd4ab14'	System	11 Aug 2020 17:01:58
User entered 'None (1)'	System	11 Aug 2020 17:01:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:51', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2f9fa674-7981-4f6e-a8d0-d71dbdd4ab14'	System	11 Aug 2020 17:01:58
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:58

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 6'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '58c7fd34-ed15-43f1-b0ef-724d8a65905a'	System	12 Aug 2020 18:21:29
User entered 'None (1)'	System	12 Aug 2020 18:21:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '58c7fd34-ed15-43f1-b0ef-724d8a65905a'	System	12 Aug 2020 18:21:29
User entered 'No (N)'	System	12 Aug 2020 18:21:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:14', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '58c7fd34-ed15-43f1-b0ef-724d8a65905a'	System	12 Aug 2020 18:21:29
User entered 'No (N)'	System	12 Aug 2020 18:21:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:17', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '58c7fd34-ed15-43f1-b0ef-724d8a65905a'	System	12 Aug 2020 18:21:29
User entered 'None (1)'	System	12 Aug 2020 18:21:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:23', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '58c7fd34-ed15-43f1-b0ef-724d8a65905a'	System	12 Aug 2020 18:21:29
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 18:21:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 7'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:16', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:24', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:26', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:30', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'None (0)'	System	07 Aug 2020 15:42:40

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:34', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered 'No (N)'	System	07 Aug 2020 15:42:40

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T10:42:37', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f85a50c2-42fd-42a3-9c74-ef946f4c7547'	System	07 Aug 2020 15:42:40
User entered '07 Aug 2020 10:42'	System	07 Aug 2020 15:42:40

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 10:41'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 13:11'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:31', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:36', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:40', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:44', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:47', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:49', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'None (0)'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:54', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered 'No (N)'	System	07 Aug 2020 19:11:59

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-07T14:11:57', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0ab152d3-2413-4726-824e-8161154d24e5'	System	07 Aug 2020 19:11:59
User entered '07 Aug 2020 14:11'	System	07 Aug 2020 19:11:59

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Aug 2020 14:06'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 2'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:11', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:13', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:17', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:19', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:23', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'None (0)'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:26', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered 'No (N)'	System	08 Aug 2020 17:15:33

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-08T12:15:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '231e5b0f-aaf2-4526-9363-8301f19bc420'	System	08 Aug 2020 17:15:33
User entered '08 Aug 2020 12:15'	System	08 Aug 2020 17:15:33

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 3'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:13', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:16', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:18', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:20', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:22', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'None (0)'	System	10 Aug 2020 09:03:36

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered 'No (N)'	System	10 Aug 2020 09:03:36

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T04:03:31', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '2df1aa87-5048-41c7-a012-9743d7c27341'	System	10 Aug 2020 09:03:36
User entered '10 Aug 2020 04:03'	System	10 Aug 2020 09:03:36

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 4'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:22:58', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:03', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:05', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:07', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:09', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'None (0)'	System	10 Aug 2020 17:23:20

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:14', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered 'No (N)'	System	10 Aug 2020 17:23:20

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-10T12:23:16', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '19f5fbde-aef9-4bdd-8b2f-8aa727a24a7b'	System	10 Aug 2020 17:23:20
User entered '10 Aug 2020 12:23'	System	10 Aug 2020 17:23:20

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 5'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:01:59', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:02', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:05', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'None (0)'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:14', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered 'No (N)'	System	11 Aug 2020 17:02:23

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-11T12:02:19', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '522fb21d-0a21-4b95-ac81-a5603ea6370e'	System	11 Aug 2020 17:02:23
User entered '11 Aug 2020 12:02'	System	11 Aug 2020 17:02:23

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 6'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:27', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:31', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:33', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:35', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:37', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'None (0)'	System	12 Aug 2020 18:21:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:39', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered 'No (N)'	System	12 Aug 2020 18:21:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-08-12T13:21:42', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'a0fbfcd0-af17-4bbc-92dd-1462c2bb8bac'	System	12 Aug 2020 18:21:46
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 18:21:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 7'	System	07 Aug 2020 15:35:46

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 15:35:46

**US3362071**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 14:17:40

**US3362071**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '15 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 14:17:40

**US3362071**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:17:40

US3362071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:17:40

US3362071

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:17:44

**US3362071**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	29 Aug 2020 14:17:44

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:02

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:02

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:02

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:02

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:08

**US3362071**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	29 Aug 2020 14:18:08

**US3362071**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:24

**US3362071**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 14:18:24

**US3362071**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:24

US3362071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:24

**US3362071**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 14:18:28

**US3362071**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	29 Aug 2020 14:18:28

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:41

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:45:41

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:45:41

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'VISIT2'	System	04 Sep 2020 15:45:41

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '08:40'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '4 Sep 2020 08:40'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '36.8' C	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '87'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'bpm'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '18'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'breaths/min'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '144'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '77'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '10:01'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '4 Sep 2020 10:01'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '36.8' C	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '84'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'bpm'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '18'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'breaths/min'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '148'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '81'	(b) (4), (b) (6)	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	04 Sep 2020 15:53:29

US3362071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:53:35

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:53:35

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '09:20'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:14:15**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '4 Sep 2020 09:20'	System	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'ONCE'	System	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 14:25:00

US3362071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:58

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:53:58

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '08:57'	(b) (4), (b) (6)	04 Sep 2020 15:53:58

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '4 Sep 2020 08:57'	System	04 Sep 2020 15:53:58

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:14:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '08:49'	(b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '4 Sep 2020 08:49'	System	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 15:54:13

US3362071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered empty.	System	04 Sep 2020 15:54:13

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:54:18

**US3362071**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	04 Sep 2020 15:54:18

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T09:59:47', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '325e6393-8e68-41f7-9f0e-6f1aaeff48e9'	System	04 Sep 2020 15:00:14
User entered 'Yes (Y)'	System	04 Sep 2020 15:00:14

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T09:59:54', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '325e6393-8e68-41f7-9f0e-6f1aaeff48e9'	System	04 Sep 2020 15:00:14
User entered '98.2'	System	04 Sep 2020 15:00:14

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T09:59:58', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '325e6393-8e68-41f7-9f0e-6f1aaeff48e9'	System	04 Sep 2020 15:00:14
User entered 'No (N)'	System	04 Sep 2020 15:00:14

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '325e6393-8e68-41f7-9f0e-6f1aaeff48e9'	System	04 Sep 2020 15:00:14
User entered '04 Sep 2020 10:00'	System	04 Sep 2020 15:00:14

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 09:40'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 12:10'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:07:38', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88216bb7-222d-4f7d-8ebe-72af0e9bda47'	System	05 Sep 2020 01:08:01
User entered 'Yes (Y)'	System	05 Sep 2020 01:08:01

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:07:48', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88216bb7-222d-4f7d-8ebe-72af0e9bda47'	System	05 Sep 2020 01:08:01
User entered '98.2'	System	05 Sep 2020 01:08:01

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:07:52', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88216bb7-222d-4f7d-8ebe-72af0e9bda47'	System	05 Sep 2020 01:08:01
User entered 'No (N)'	System	05 Sep 2020 01:08:01

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:07:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '88216bb7-222d-4f7d-8ebe-72af0e9bda47'	System	05 Sep 2020 01:08:01
User entered '04 Sep 2020 20:07'	System	05 Sep 2020 01:08:01

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 13:05'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 2'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered 'Yes (Y)'	System	05 Sep 2020 19:42:40

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:16', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered '98.2'	System	05 Sep 2020 19:42:40

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:20', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered 'Yes (Y)'	System	05 Sep 2020 19:42:40

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
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 'subject states that he take any medication' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 08:29:45
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).	(b) (4), (b) (6)	25 Sep 2020 18:14:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:30', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered '1'	System	05 Sep 2020 19:42:40

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:30', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered '0'	System	05 Sep 2020 19:42:40

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:37', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd450208e-579a-4a54-842a-d28dfbc616c2'	System	05 Sep 2020 19:42:40
User entered '05 Sep 2020 14:42'	System	05 Sep 2020 19:42:40

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 3'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 4'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 5'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 6'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 7'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:44', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e81d2d93-b3f5-455c-8da6-1005db50e897'	System	04 Sep 2020 15:01:01
User entered 'None (1)'	System	04 Sep 2020 15:01:01

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:47', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e81d2d93-b3f5-455c-8da6-1005db50e897'	System	04 Sep 2020 15:01:01
User entered 'No (N)'	System	04 Sep 2020 15:01:01

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:50', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e81d2d93-b3f5-455c-8da6-1005db50e897'	System	04 Sep 2020 15:01:01
User entered 'No (N)'	System	04 Sep 2020 15:01:01

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:54', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e81d2d93-b3f5-455c-8da6-1005db50e897'	System	04 Sep 2020 15:01:01
User entered 'None (1)'	System	04 Sep 2020 15:01:01

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:00:57', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e81d2d93-b3f5-455c-8da6-1005db50e897'	System	04 Sep 2020 15:01:01
User entered '04 Sep 2020 10:00'	System	04 Sep 2020 15:01:01

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 09:40'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 12:10'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:50', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8b239475-a961-4bc6-9423-1dd57b0adc46'	System	05 Sep 2020 01:09:13
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:09:13

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:09:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8b239475-a961-4bc6-9423-1dd57b0adc46'	System	05 Sep 2020 01:09:13
User entered 'No (N)'	System	05 Sep 2020 01:09:13

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:09:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8b239475-a961-4bc6-9423-1dd57b0adc46'	System	05 Sep 2020 01:09:13
User entered 'No (N)'	System	05 Sep 2020 01:09:13

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:09:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8b239475-a961-4bc6-9423-1dd57b0adc46'	System	05 Sep 2020 01:09:13
User entered 'None (1)'	System	05 Sep 2020 01:09:13

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:09:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8b239475-a961-4bc6-9423-1dd57b0adc46'	System	05 Sep 2020 01:09:13
User entered '04 Sep 2020 20:09'	System	05 Sep 2020 01:09:13

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 13:05'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 2'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'interferes with activity. no con med reported' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:31:43
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	Amy Thomassie (b) (4)	23 Feb 2021 22:15:15
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 17:27:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:55', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1e0e5b55-4a64-4d85-8cb3-19936f5c1120'	System	05 Sep 2020 19:43:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Sep 2020 19:43:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:42:57', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1e0e5b55-4a64-4d85-8cb3-19936f5c1120'	System	05 Sep 2020 19:43:10
User entered 'No (N)'	System	05 Sep 2020 19:43:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1e0e5b55-4a64-4d85-8cb3-19936f5c1120'	System	05 Sep 2020 19:43:10
User entered 'No (N)'	System	05 Sep 2020 19:43:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:03', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1e0e5b55-4a64-4d85-8cb3-19936f5c1120'	System	05 Sep 2020 19:43:10
User entered 'None (1)'	System	05 Sep 2020 19:43:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:06', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '1e0e5b55-4a64-4d85-8cb3-19936f5c1120'	System	05 Sep 2020 19:43:10
User entered '05 Sep 2020 14:43'	System	05 Sep 2020 19:43:10

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 3'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 4'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 5'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 6'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 7'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:14:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:01', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'None (0)'	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:03', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'None (0)'	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:06', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'None (0)'	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328' User entered 'None (0)'	System	04 Sep 2020 15:01:22
	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:10', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'None (0)'	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:13', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'None (0)'	System	04 Sep 2020 15:01:22

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:15', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered 'No (N)'	System	04 Sep 2020 15:01:22

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T10:01:18', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b3ac4b04-bff8-48a6-8dfb-7133f8d53328'	System	04 Sep 2020 15:01:22
User entered '04 Sep 2020 10:01'	System	04 Sep 2020 15:01:22

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 09:40'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 12:10'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:03', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:12', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:20', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:24', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:32', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'None (0)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:36', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered 'No (N)'	System	05 Sep 2020 01:08:45

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-04T20:08:39', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'd4ce88f7-fc1e-4c76-9f13-e762f5b09c4e'	System	05 Sep 2020 01:08:45
User entered '04 Sep 2020 20:08'	System	05 Sep 2020 01:08:45

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '04 Sep 2020 13:05'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 2'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:11', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'None (0)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:13', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'None (0)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:15', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'None (0)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:17', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'None (0)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:19', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'None (0)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:22', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:25', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered 'No (N)'	System	05 Sep 2020 19:43:30

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-09-05T14:43:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '45fc9483-bbf1-4b02-ab23-2e6e7f1470c0'	System	05 Sep 2020 19:43:30
User entered '05 Sep 2020 14:43'	System	05 Sep 2020 19:43:30

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 3'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 4'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 5'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 6'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:14:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	04 Sep 2020 14:25:00
User entered 'Day 7'	System	04 Sep 2020 14:25:00

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

US3362071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:14:15

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)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:14:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:25:00

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:37:11

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '12 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 17:37:11

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 17:37:11

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 17:37:11

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 17:37:00

**US3362071**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	12 Sep 2020 17:37:00

**US3362071**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:36:56

**US3362071**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 14:36:56

**US3362071**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:36:56

US3362071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 14:36:56

US3362071

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 14:37:00

**US3362071**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	18 Sep 2020 14:37:00

US3362071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:03:08

**US3362071**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:03:08

**US3362071**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:03:08

**US3362071**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 20:03:08

US3362071

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:03:12

**US3362071**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	29 Sep 2020 20:03:12

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:05:31

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:05:31

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:05:31

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'VISIT3'	System	29 Sep 2020 20:05:31

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '08:38'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '29 Sep 2020 08:38'	System	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '89'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'bpm'	System	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '18'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'breaths/min'	System	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '145'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	29 Sep 2020 20:10:22

US3362071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '82'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'mmHg'	System	29 Sep 2020 20:10:22

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55

US3362071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:29

US3362071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:29

US3362071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:58

US3362071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:58

US3362071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered '08:54'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:10:58

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered '29 Sep 2020 08:54'	System	29 Sep 2020 20:10:58

US3362071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:29:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:11:02

**US3362071**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	29 Sep 2020 20:11:02

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 64'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-07T15:06:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f40c57fe-a98f-48af-b74b-8ce1f264b4be'	System	07 Oct 2020 20:06:52
User entered 'No (N)'	System	07 Oct 2020 20:06:52

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-07T15:06:45', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f40c57fe-a98f-48af-b74b-8ce1f264b4be'	System	07 Oct 2020 20:06:52
User entered 'No (N)'	System	07 Oct 2020 20:06:52

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-07T15:06:49', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f40c57fe-a98f-48af-b74b-8ce1f264b4be'	System	07 Oct 2020 20:06:52
User entered '07 Oct 2020 15:06:49'	System	07 Oct 2020 20:06:52

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 71'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-14T13:12:58', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '459153d0-188e-45af-bdb0-8ea74d733da5'	System	14 Oct 2020 18:13:12
User entered 'No (N)'	System	14 Oct 2020 18:13:12

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-14T13:13:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '459153d0-188e-45af-bdb0-8ea74d733da5'	System	14 Oct 2020 18:13:12
User entered 'No (N)'	System	14 Oct 2020 18:13:12

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-14T13:13:08', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '459153d0-188e-45af-bdb0-8ea74d733da5'	System	14 Oct 2020 18:13:12
User entered '14 Oct 2020 13:13:08'	System	14 Oct 2020 18:13:12

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 78'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-21T12:59:05', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '9b4d61b5-e658-4ac7-8852-0f2779609fb2'	System	21 Oct 2020 17:59:21
User entered 'No (N)'	System	21 Oct 2020 17:59:21

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-21T12:59:12', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '9b4d61b5-e658-4ac7-8852-0f2779609fb2'	System	21 Oct 2020 17:59:21
User entered 'No (N)'	System	21 Oct 2020 17:59:21

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-10-21T12:59:15', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '9b4d61b5-e658-4ac7-8852-0f2779609fb2'	System	21 Oct 2020 17:59:21
User entered '21 Oct 2020 12:59:15'	System	21 Oct 2020 17:59:21

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 92'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-04T05:46:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e1765184-29f3-4e96-96f6-3d4da71bbe7f'	System	04 Nov 2020 11:46:53
User entered 'No (N)'	System	04 Nov 2020 11:46:53

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-04T05:46:27', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e1765184-29f3-4e96-96f6-3d4da71bbe7f'	System	04 Nov 2020 11:46:53
User entered 'No (N)'	System	04 Nov 2020 11:46:53

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-04T05:46:32', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e1765184-29f3-4e96-96f6-3d4da71bbe7f' User entered '04 Nov 2020 05:46:32'	System	04 Nov 2020 11:46:53
	System	04 Nov 2020 11:46:53

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 99'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-11T07:43:40', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c6150ab6-f263-4c05-bbf6-01644e922be0'	System	11 Nov 2020 13:43:54
User entered 'No (N)'	System	11 Nov 2020 13:43:54

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-11T07:43:48', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c6150ab6-f263-4c05-bbf6-01644e922be0'	System	11 Nov 2020 13:43:54
User entered 'No (N)'	System	11 Nov 2020 13:43:54

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-11T07:43:51', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c6150ab6-f263-4c05-bbf6-01644e922be0'	System	11 Nov 2020 13:43:54
User entered '11 Nov 2020 07:43:51'	System	11 Nov 2020 13:43:54

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered 'Day 106'	System	07 Aug 2020 15:35:46

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-18T05:05:47', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8fd3341d-2fe3-42fd-8cbb-681c364a73e9'	System	18 Nov 2020 11:06:03
User entered 'No (N)'	System	18 Nov 2020 11:06:03

US3362071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-18T05:05:51', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8fd3341d-2fe3-42fd-8cbb-681c364a73e9'	System	18 Nov 2020 11:06:03
User entered 'No (N)'	System	18 Nov 2020 11:06:03

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-18T05:05:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '8fd3341d-2fe3-42fd-8cbb-681c364a73e9'	System	18 Nov 2020 11:06:03
User entered '18 Nov 2020 05:05:56'	System	18 Nov 2020 11:06:03

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:18:29
Data entry locked.	System	07 Aug 2020 15:35:46
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 15:35:46

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2020-11-22T08:12:26', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '523072cd-66d7-459c-ab82-fe3487fa32c8'	System	22 Nov 2020 14:12:37
User entered 'No (N)'	System	22 Nov 2020 14:12:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2020-11-22T08:12:30', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '523072cd-66d7-459c-ab82-fe3487fa32c8'	System	22 Nov 2020 14:12:37
User entered 'No (N)'	System	22 Nov 2020 14:12:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-11-22T08:12:33', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '523072cd-66d7-459c-ab82-fe3487fa32c8'	System	22 Nov 2020 14:12:37
User entered '22 Nov 2020 08:12:33'	System	22 Nov 2020 14:12:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2020-12-01T13:20:25', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered 'Yes (Y)'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2020-12-01T13:20:30', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered 'No (N)'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2020-12-01T13:20:36', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered 'No (N)'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2020-12-01T13:20:53', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered 'Yes (Y)'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Please 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 (f7c07c033dda00e7)', Time: '2020-12-01T13:21:06', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2020-12-01T13:21:12', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '588963d0-ac1a-4111-9b9a-b6e4e101f77c'	System	01 Dec 2020 19:21:22
User entered '01 Dec 2020 13:21:12'	System	01 Dec 2020 19:21:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-03T05:25:51', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '21ee9042-4cae-420c-8828-0c88f8590cee'	System	03 Jan 2021 11:26:22
User entered 'No (N)'	System	03 Jan 2021 11:26:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-01-03T05:26:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '21ee9042-4cae-420c-8828-0c88f8590cee'	System	03 Jan 2021 11:26:22
User entered 'No (N)'	System	03 Jan 2021 11:26:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-01-03T05:26:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '21ee9042-4cae-420c-8828-0c88f8590cee' User entered '03 Jan 2021 05:26:04'	System	03 Jan 2021 11:26:22
	System	03 Jan 2021 11:26:22

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-10T08:00:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ee5408e7-97e7-479c-ab74-a858ba89d20f'	System	10 Jan 2021 14:00:38
User entered 'No (N)'	System	10 Jan 2021 14:00:38

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-01-10T08:00:26', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ee5408e7-97e7-479c-ab74-a858ba89d20f'	System	10 Jan 2021 14:00:38
User entered 'No (N)'	System	10 Jan 2021 14:00:38

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-01-10T08:00:29', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ee5408e7-97e7-479c-ab74-a858ba89d20f' User entered '10 Jan 2021 08:00:29'	System	10 Jan 2021 14:00:38
	System	10 Jan 2021 14:00:38

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-17T09:03:47', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6'	System	17 Jan 2021 15:04:37
User entered 'Yes (Y)'	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-01-17T09:03:54', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6'	System	17 Jan 2021 15:04:37
User entered 'No (N)'	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-17T09:04:02', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6'	System	17 Jan 2021 15:04:37
User entered 'No (N)'	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-17T09:04:14', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6'	System	17 Jan 2021 15:04:37
User entered 'Yes (Y)'	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Please 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 (f7c07c033dda00e7)', Time: '2021-01-17T09:04:21', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6'	System	17 Jan 2021 15:04:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-01-17T09:04:24', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b5cd849b-16c5-4f8b-b54a-8a1aca4404c6' User entered '17 Jan 2021 09:04:24'	System	17 Jan 2021 15:04:37
	System	17 Jan 2021 15:04:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-24T05:11:27', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ce87664c-0e4b-4ae0-919c-6f92b1702c8e'	System	24 Jan 2021 11:11:37
User entered 'No (N)'	System	24 Jan 2021 11:11:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-01-24T05:11:31', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ce87664c-0e4b-4ae0-919c-6f92b1702c8e'	System	24 Jan 2021 11:11:37
User entered 'No (N)'	System	24 Jan 2021 11:11:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-01-24T05:11:34', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'ce87664c-0e4b-4ae0-919c-6f92b1702c8e' User entered '24 Jan 2021 05:11:34'	System	24 Jan 2021 11:11:37
	System	24 Jan 2021 11:11:37

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-01-31T02:48:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b224307b-8e90-4ad4-b1ef-7ae988d9bbea'	System	31 Jan 2021 08:48:09
User entered 'No (N)'	System	31 Jan 2021 08:48:09

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-01-31T02:48:04', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b224307b-8e90-4ad4-b1ef-7ae988d9bbea'	System	31 Jan 2021 08:48:09
User entered 'No (N)'	System	31 Jan 2021 08:48:09

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-01-31T02:48:07', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'b224307b-8e90-4ad4-b1ef-7ae988d9bbea'	System	31 Jan 2021 08:48:09
User entered '31 Jan 2021 02:48:07'	System	31 Jan 2021 08:48:09

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-02-07T09:03:38', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '18cf0e08-e0b6-43e6-beb6-46b2d01d263d'	System	07 Feb 2021 15:03:51
User entered 'No (N)'	System	07 Feb 2021 15:03:51

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-02-07T09:03:42', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '18cf0e08-e0b6-43e6-beb6-46b2d01d263d'	System	07 Feb 2021 15:03:51
User entered 'No (N)'	System	07 Feb 2021 15:03:51

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-07T09:03:45', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '18cf0e08-e0b6-43e6-beb6-46b2d01d263d' User entered '07 Feb 2021 09:03:45'	System	07 Feb 2021 15:03:51
	System	07 Feb 2021 15:03:51

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-02-14T02:46:56', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'af03c5e7-e5cd-4638-b535-e6e1c5b033f0'	System	14 Feb 2021 08:47:07
User entered 'No (N)'	System	14 Feb 2021 08:47:07

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-02-14T02:46:59', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'af03c5e7-e5cd-4638-b535-e6e1c5b033f0'	System	14 Feb 2021 08:47:07
User entered 'No (N)'	System	14 Feb 2021 08:47:07

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-14T02:47:02', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'af03c5e7-e5cd-4638-b535-e6e1c5b033f0'	System	14 Feb 2021 08:47:07
User entered '14 Feb 2021 02:47:02'	System	14 Feb 2021 08:47:07

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-02-21T03:13:28', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '4f499b1b-9ae4-47ec-98fb-563b216f63fe'	System	21 Feb 2021 09:13:43
User entered 'No (N)'	System	21 Feb 2021 09:13:43

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-02-21T03:13:38', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '4f499b1b-9ae4-47ec-98fb-563b216f63fe'	System	21 Feb 2021 09:13:43
User entered 'No (N)'	System	21 Feb 2021 09:13:43

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-21T03:13:41', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '4f499b1b-9ae4-47ec-98fb-563b216f63fe' User entered '21 Feb 2021 03:13:41'	System	21 Feb 2021 09:13:43
	System	21 Feb 2021 09:13:43

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-02-28T04:24:35-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f2357158-20c2-45c9-bf99-e1821108dcda' User entered 'No (N)'	System	28 Feb 2021 10:24:47
	System	28 Feb 2021 10:24:47

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-02-28T04:24:38-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f2357158-20c2-45c9-bf99-e1821108dcda' User entered 'No (N)'	System	28 Feb 2021 10:24:47

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-28T04:24:41-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'f2357158-20c2-45c9-bf99-e1821108dcda' User entered '28 Feb 2021 04:24:41'	System	28 Feb 2021 10:24:47
	System	28 Feb 2021 10:24:47

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:44:11

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-11T07:29:51-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered 'Yes (Y)'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-03-11T07:29:54-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered 'No (N)'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-11T07:29:58-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered 'No (N)'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-11T07:30:03-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered 'Yes (Y)'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Please 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 (f7c07c033dda00e7)', Time: '2021-03-11T07:30:10-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-03-11T07:30:15-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'c91962a9-6d0f-4ea7-90c7-2dd0fa33b312'	System	11 Mar 2021 13:30:25
User entered '11 Mar 2021 07:30:15'	System	11 Mar 2021 13:30:25

**US3362071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-14T04:10:01-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '7dc74dba-c3cd-4a0f-86ee-4afeda3d1761'	System	14 Mar 2021 09:10:13
User entered 'No (N)'	System	14 Mar 2021 09:10:13

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-03-14T04:10:05-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '7dc74dba-c3cd-4a0f-86ee-4afeda3d1761'	System	14 Mar 2021 09:10:13
User entered 'No (N)'	System	14 Mar 2021 09:10:13

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-03-14T04:10:08-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '7dc74dba-c3cd-4a0f-86ee-4afeda3d1761'	System	14 Mar 2021 09:10:13
User entered '14 Mar 2021 04:10:08'	System	14 Mar 2021 09:10:13

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-21T03:44:02-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '55784adb-125f-468b-9a46-31a3e3f21159'	System	21 Mar 2021 08:44:11
User entered 'No (N)'	System	21 Mar 2021 08:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-03-21T03:44:05-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '55784adb-125f-468b-9a46-31a3e3f21159'	System	21 Mar 2021 08:44:11
User entered 'No (N)'	System	21 Mar 2021 08:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-03-21T03:44:07-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '55784adb-125f-468b-9a46-31a3e3f21159'	System	21 Mar 2021 08:44:11
User entered '21 Mar 2021 03:44:07'	System	21 Mar 2021 08:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-03-28T10:58:45-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '5d42b291-5ee0-489d-a702-62f90e751c05'	System	28 Mar 2021 15:58:55
User entered 'No (N)'	System	28 Mar 2021 15:58:55

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-03-28T10:58:49-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '5d42b291-5ee0-489d-a702-62f90e751c05'	System	28 Mar 2021 15:58:55
User entered 'No (N)'	System	28 Mar 2021 15:58:55

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-03-28T10:58:52-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '5d42b291-5ee0-489d-a702-62f90e751c05'	System	28 Mar 2021 15:58:55
User entered '28 Mar 2021 10:58:52'	System	28 Mar 2021 15:58:55

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-04-05T12:50:10-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '078941b1-e1f3-4cbc-8ac7-2453a8daae25'	System	05 Apr 2021 17:50:20
User entered 'No (N)'	System	05 Apr 2021 17:50:20

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-04-05T12:50:13-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '078941b1-e1f3-4cbc-8ac7-2453a8daae25'	System	05 Apr 2021 17:50:20
User entered 'No (N)'	System	05 Apr 2021 17:50:20

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-04-05T12:50:16-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '078941b1-e1f3-4cbc-8ac7-2453a8daae25'	System	05 Apr 2021 17:50:20
User entered '05 Apr 2021 12:50:16'	System	05 Apr 2021 17:50:20

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-04-11T11:25:15-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e92b1e1e-246c-4597-ad06-277ea8c304f2'	System	11 Apr 2021 16:25:24
User entered 'No (N)'	System	11 Apr 2021 16:25:24

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-04-11T11:25:18-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e92b1e1e-246c-4597-ad06-277ea8c304f2'	System	11 Apr 2021 16:25:24
User entered 'No (N)'	System	11 Apr 2021 16:25:24

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-04-11T11:25:21-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e92b1e1e-246c-4597-ad06-277ea8c304f2' User entered '11 Apr 2021 11:25:21'	System	11 Apr 2021 16:25:24
	System	11 Apr 2021 16:25:24

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-04-20T19:54:08-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0dac853e-85dd-439c-a518-1d8c9402333c' User entered 'No (N)'	System	21 Apr 2021 00:54:17
	System	21 Apr 2021 00:54:17

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-04-20T19:54:10-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0dac853e-85dd-439c-a518-1d8c9402333c'	System	21 Apr 2021 00:54:17
User entered 'No (N)'	System	21 Apr 2021 00:54:17

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-04-20T19:54:13-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '0dac853e-85dd-439c-a518-1d8c9402333c' User entered '20 Apr 2021 19:54:13'	System	21 Apr 2021 00:54:17

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-04-26T09:02:25-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e2198bfb-dfc7-42da-b973-ea4943c2c520'	System	26 Apr 2021 14:02:31
User entered 'No (N)'	System	26 Apr 2021 14:02:31

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-04-26T09:02:27-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e2198bfb-dfc7-42da-b973-ea4943c2c520'	System	26 Apr 2021 14:02:31
User entered 'No (N)'	System	26 Apr 2021 14:02:31

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-04-26T09:02:29-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e2198bfb-dfc7-42da-b973-ea4943c2c520'	System	26 Apr 2021 14:02:31
User entered '26 Apr 2021 09:02:29'	System	26 Apr 2021 14:02:31

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[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 (f7c07c033dda00e7)', Time: '2021-05-02T04:44:30-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '48b08ee4-2a80-4535-97bc-932d5060b6af'	System	02 May 2021 09:44:41
User entered 'No (N)'	System	02 May 2021 09:44:41

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

Have you been exposed to someone with 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 (f7c07c033dda00e7)', Time: '2021-05-02T04:44:35-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '48b08ee4-2a80-4535-97bc-932d5060b6af'	System	02 May 2021 09:44:41
User entered 'No (N)'	System	02 May 2021 09:44:41

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-05-02T04:44:38-05:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: '48b08ee4-2a80-4535-97bc-932d5060b6af'	System	02 May 2021 09:44:41
User entered '02 May 2021 04:44:38'	System	02 May 2021 09:44:41

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:44:11

**US3362071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:14:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:44:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:44:11

US3362071

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:14:15**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-28T04:24:24-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e7d18541-35dd-4f97-ac42-1b3a02f1201f' User entered 'No (N)'	System	28 Feb 2021 10:24:33
	System	28 Feb 2021 10:24:33

**US3362071**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f7c07c033dda00e7)', Time: '2021-02-28T04:24:28-06:00', User OID: 'PatientReportedOutcome (US3362071)', ODM File OID: 'e7d18541-35dd-4f97-ac42-1b3a02f1201f' User entered '28 Feb 2021 04:24:28'	System	28 Feb 2021 10:24:33
	System	28 Feb 2021 10:24:33

**US3362071**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:56

**US3362071**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:39
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:56

**US3362071**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:56

US3362071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:39
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:56

**US3362071**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:17:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:48:04

**US3362071**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:14:55
User entered 'I'	System	27 Oct 2020 19:48:04

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:30:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 17:15:50

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:30:16
User entered '01 Dec 2020'	(b) (4), (b) (6)	01 Dec 2020 17:15:50

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 17:15:50

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:30:16
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 17:15:50

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:30:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 17:15:55

**US3362071**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User entered 'I'	System	01 Dec 2020 17:15:55

**US3362071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:31:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 22:00:32

**US3362071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:31:33
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 22:00:32

**US3362071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:31:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Dec 2020 22:00:32

US3362071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:31:33
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 22:00:32

**US3362071**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:31:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 22:00:37

**US3362071**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User entered 'I'	System	30 Dec 2020 22:00:37

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:22
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Mar 2021 20:18:02

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:22
User entered '01 Feb 2021'	Amy Thomassie (b) (4)	19 Mar 2021 20:18:02

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:22
User entered 'Contact Made (CONTACT MADE)'	Amy Thomassie (b) (4)	19 Mar 2021 20:18:02

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:22
User entered empty.	Amy Thomassie (b) (4)	19 Mar 2021 20:18:02

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:35:52

**US3362071**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:18:45
User entered 'I'	System	26 Feb 2021 15:35:52

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:36:12

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:53
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:36:12

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Feb 2021 15:36:12

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered 'VISIT4'	System	26 Feb 2021 15:36:12

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered 'No (N)'	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered empty.	System	30 Mar 2021 18:30:10

US3362071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered empty.	System	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

US3362071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered empty.	System	30 Mar 2021 18:30:10

US3362071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered empty.	System	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:32:59
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:30:10

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered empty.	System	30 Mar 2021 18:30:10

US3362071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:07
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:36:26

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:07
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:36:26

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:33
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Mar 2021 20:19:02

US3362071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:33
User entered '26 Feb 2021'	Amy Thomassie (b) (4)	19 Mar 2021 20:19:02

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:33
User entered '09:09'	Amy Thomassie (b) (4)	19 Mar 2021 20:19:02

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered '26 Feb 2021 09:09'	System	19 Mar 2021 20:19:02

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:33:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:36:57

**US3362071**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:30:43
User entered 'I'	System	26 Feb 2021 15:36:57

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:33:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 14:13:00

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:33:52
User entered '2 Apr 2021'	(b) (4), (b) (6)	02 Apr 2021 14:13:00

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:33:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Apr 2021 14:13:00

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:14:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 17:33:52
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 14:13:00
	(b) (4), (b) (6)	

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:33:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 14:13:05

**US3362071**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 14:13:05

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:35:09
User entered '07 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:12:32

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:14:15**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:35:09
User entered '13:24'	(b) (4), (b) (6)	11 Dec 2020 17:12:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:14:15

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:24
User entered '07 Dec 2020 13:24'	System	11 Dec 2020 17:12:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:14:15

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:35:09
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error		11 Dec 2020 17:44:24
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'		11 Dec 2020 17:12:32

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:14:15**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:35:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:12:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 17:43:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 17:13:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 17:13:36
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:13:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:13:11
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:11

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '24 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:13:36

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:36

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:13:50

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '25 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:14:15**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:13:50

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '26 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:01

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:14:17

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '27 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:14:17

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:17

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:14:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '28 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '29 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:14:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:15:06

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '30 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:06

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 17:43:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Dec 2020 17:16:32
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:16:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Dec 2020 17:15:49
User entered '31 Nov 2020' (non-conformant).	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:15:49

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '02 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '1' reason for change: Data Entry Error		11 Dec 2020 17:16:37
User entered '0'		11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:32

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:43:52
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:17:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 17:17:13
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:17:13
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:16:58
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 17:43:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:17:13
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:16:58

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	11 Dec 2020 17:17:28

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '04 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:28

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 13 (Day 13)'	(b) (4), (b) (6)	11 Dec 2020 17:17:39

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '05 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:39

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '06 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 17:43:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:18:07
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:17:48

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	11 Dec 2020 17:18:02

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '07 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 17:14:15**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:02

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	11 Dec 2020 17:18:31

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '08 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 17:14:15**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:31

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	11 Dec 2020 17:18:46

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '09 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'l'	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered empty.	System	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:18:46

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '95'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '36.7' C	(b) (4), (b) (6)	11 Dec 2020 17:20:53

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	11 Dec 2020 17:20:53

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '11 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98.4' F	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:25:10

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:26:41

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '12 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '97'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '99.6' F	(b) (4), (b) (6)	14 Dec 2020 17:26:41

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 17:14:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 17:14:15**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 09 Jun 2021 17:14:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:26:41

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 17:32:30

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 17:14:15**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '13 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '97.2' F	(b) (4), (b) (6)	14 Dec 2020 17:32:30

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 17:14:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 17:14:15**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 09 Jun 2021 17:14:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 17:32:30

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 22 (Day 22)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '14 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '99.2' F	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:56:33

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered 'Day 23 (Day 23)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '15 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User entered '%'	System	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered '98.1' F	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'Severe (Severe)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:14:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:43:52
User entered 'None (None)'	(b) (4), (b) (6)	15 Dec 2020 16:57:40

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:21:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:14:15**

[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 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

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 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:52:11
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:31:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:31:07
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	15 Dec 2020 14:31:07
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:39:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:39:59
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	11 Dec 2020 17:39:49
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered by data change (Site from System).	System	11 Dec 2020 17:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:39:49
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:21:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 17:21:57
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	11 Dec 2020 17:21:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:21:57
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 17:21:37
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:21:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

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 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:52:11
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	11 Dec 2020 17:21:57
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	11 Dec 2020 17:21:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 17:21:37

**US3362071**

**Folder: Covid-19 Assessment 07 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:14:15**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:52:11
User entered empty; reason for change Data Entry Error		11 Dec 2020 17:21:57
User entered 'Yes (Y)'		11 Dec 2020 17:21:37

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:14:15

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:36
User entered '0'	System	11 Dec 2020 17:39:49
User entered '1'	System	11 Dec 2020 17:21:57

US3362071

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:14:15

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:52:16
User entered 'Yes (Y)' reason for change: Data Entry Error		11 Dec 2020 17:27:51
User entered 'No (N)' reason for change: Data Entry Error		11 Dec 2020 17:25:26
User entered 'Yes (Y)'		11 Dec 2020 17:25:14

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered empty.	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 5 (Day 5)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered 'Yes (Y)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered '14 Dec 2020'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 7 (Day 7)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:58:47
	Alexandra Caillouet	
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 9 (Day 9)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

US3362071

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:14:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered 'NA (COVID-19 Negative) (NA)'	Alexandra Caillouet	21 Dec 2020 21:59:07
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered empty.	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 14 (Day 14)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered 'NA (COVID-19 Negative) (NA)'	Alexandra Caillouet	21 Dec 2020 21:59:07
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered empty.	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 21 (Day 21)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered 'NA (COVID-19 Negative) (NA)'	Alexandra Caillouet	21 Dec 2020 21:59:07
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered empty.	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User accepted default value 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:11:21
User entered 'NA (COVID-19 Negative) (NA)'	Alexandra Caillouet	21 Dec 2020 21:59:07
reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	21 Dec 2020 21:58:47
	(b) (4)	

**US3362071**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:11:21
User entered empty.	Alexandra Caillouet (b) (4)	21 Dec 2020 21:58:47

US3362071

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:52:35
Query 'Per ETRTR, Please complete Saliva Collection Page. Thanks!' canceled (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 16:37:25
Comment added 'Saliva Collection log updated.'	Alexandra Caillouet	21 Dec 2020 22:00:37
User opened query 'Per ETRTR, Please complete Saliva Collection Page. Thanks!' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 20:32:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:52:35
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:52:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User entered 'SICKD1'	System	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '10:13'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User entered '10 Dec 2020 10:13'	System	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '181' cm	(b) (4), (b) (6)	11 Dec 2020 18:01:53
DataPoint set to visible.	System	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '140' kg	(b) (4), (b) (6)	11 Dec 2020 18:01:53
DataPoint set to visible.	System	11 Dec 2020 17:48:03

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '36.7' C	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '107'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User entered 'bpm'	System	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '20'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

US3362071

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User entered 'breaths/min'	System	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '117'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User entered 'mmHg'	System	11 Dec 2020 18:01:53

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:14:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:53:11
User entered '79'	(b) (4), (b) (6)	11 Dec 2020 18:01:53

US3362071

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29
User entered 'mmHg'	System	11 Dec 2020 18:01:53

US3362071

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29

US3362071

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:29

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:54:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:02:09

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:14:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:54:17
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:02:09

US3362071

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:14:15

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:54:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:04:30

**US3362071**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:14:15**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:44
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:54:23
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:04:30

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:37:15

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:15

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Feb 2021 15:37:15

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:14:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User entered 'UNBLND_DECIDE'	System	26 Feb 2021 15:37:15

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:14:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:51:13

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:51:13

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:14:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:14:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:14:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:29

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:14:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User entered empty.	System	26 Feb 2021 15:37:29

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:14:15**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User entered empty.	System	26 Feb 2021 15:37:29

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:38:00

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:38:00

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '09:09'	(b) (4), (b) (6)	26 Feb 2021 15:38:00

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:14:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User entered '26 Feb 2021 09:09'	System	26 Feb 2021 15:38:00

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:38:12

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '26 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:38:12

US3362071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered '09:13'	(b) (4), (b) (6)	26 Feb 2021 15:38:12

**US3362071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:14:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:58:52
User entered '26 Feb 2021 09:13'	System	26 Feb 2021 15:38:12

US3362071

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:14:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:12
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:10:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 21:45:59
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:23:29

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:52:11
User entered 'USA-US112-2020-mRNA-1273-P301000013'	System	09 Dec 2020 22:18:22
User entered 'New'	(b) (4), (b) (6)	09 Dec 2020 22:18:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per MM, please update the AE term to the confirmed diagnosis, as per the SAE narrative.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:36:37
Query 'Per MM, please update the AE term to the confirmed diagnosis, as per the SAE narrative.' answered with 'unable to receive medical records that show the positive result, multiple request made, hospital notes indicate + covid test at outside site prior to admission, but no results sent when requested' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:59:10
User opened query 'Per MM, please update the AE term to the confirmed diagnosis, as per the SAE narrative.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:29:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:54:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:54:58
Data point term sent to Coder	System	15 Dec 2020 16:53:53
Coding entries removed.	(b) (4), (b) (6)	15 Dec 2020 16:53:50
User entered 'upper respiratory infection' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:53:50
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 19:00:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 19:00:48
Data point term sent to Coder	System	14 Dec 2020 19:00:22
Coding entries removed.	(b) (4), (b) (6)	14 Dec 2020 19:00:14
User entered 'suspected COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 19:00:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 15:13:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 15:13:57
Data point term sent to Coder	System	08 Dec 2020 15:13:08
User entered 'symptomatic COVID-19'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 20:09:11
User closed query 'Data is required. Please complete.' (Site from System).	Alexandra Caillouet	14 Jan 2021 20:09:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	08 Dec 2020 15:16:43
User entered '03 Dec 2020' reason for change: Data Entry Error	System	08 Dec 2020 15:16:43
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 15:16:43
User entered empty.	System	08 Dec 2020 15:12:19
	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:36:43
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'end date updated ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:52:40
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:48:36
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:05:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:09:11
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Jan 2021 22:44:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:44:58
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Jan 2021 22:38:29
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 18:04:35
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 13:55:35
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 15:13:28

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 15:13:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:13:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 15:12:19
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	24 Mar 2021 14:51:21
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Mar 2021 14:51:21
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Mar 2021 14:50:38
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Mar 2021 14:50:38
User entered '30 Dec 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	24 Mar 2021 14:50:38
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Mar 2021 14:48:36
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Jan 2021 20:10:48
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Jan 2021 20:10:48
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Jan 2021 20:09:11
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:09:11
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Jan 2021 22:38:29
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	12 Jan 2021 22:38:29

US3362071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:38:29
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Jan 2021 22:38:09
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 18:04:35
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	31 Dec 2020 18:04:35
User entered empty; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	31 Dec 2020 18:04:35
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Dec 2020 13:55:35
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 13:55:35
Query 'PV Query: Please provide the event end date for the event, upper respiratory infection (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)	30 Dec 2020 21:10:50
User opened query 'PV Query: Please provide the event end date for the event, upper respiratory infection (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)	30 Dec 2020 21:10:40
User closed query 'PV Query: Please provide the event end date for the event, upper respiratory infection (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)	17 Dec 2020 16:02:12
Query 'PV Query: Please provide the event end date for the event, upper respiratory infection (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated as ongoing ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:34:29

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date for the event, upper respiratory infection (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	16 Dec 2020 18:22:49
	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date for the event, upper respiratory infection (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)	02 Apr 2021 13:50:35
User opened query 'PV Query: Please provide the event end date for the event, upper respiratory infection (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)	22 Dec 2020 14:52:49
User entered empty.	System	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please consider updating the hospital admission date to the date of the ER visit (03 Dec 2020), where the subject stayed until 05 Dec 2020 the date of discharge.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 15:36:11
Query 'PV Query: Please consider updating the hospital admission date to the date of the ER visit (03 Dec 2020), where the subject stayed until 05 Dec 2020 the date of discharge.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4) (b) (4)	07 Jan 2021 22:26:29
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 13:55:35
User opened query 'PV Query: Please consider updating the hospital admission date to the date of the ER visit (03 Dec 2020), where the subject stayed until 05 Dec 2020 the date of discharge.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 21:11:27
User entered '4 Dec 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	08 Dec 2020 16:00:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:58
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:12:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:19
User entered '04 ' (non-conformant).	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:58
User entered '5 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:12:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Dec 2020 15:12:19
User entered '5 ' (non-conformant).	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4)	08 Dec 2020 16:00:28
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4)	08 Dec 2020 16:00:28
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Form: Adverse Events (1)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:43:04
Query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:57:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:51:21
User opened query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 21:08:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:10:48
User closed query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:44:39
Query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 22:39:16

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Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:38:09
User opened query 'PV Query: Please provide the final event outcome for event, upper respiratory infection, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:51:56
User closed query 'PV Query: Please provide the final event outcome for event, upper respiratory infection , when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:02:27
Query 'PV Query: Please provide the final event outcome for event, upper respiratory infection , when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated ongoing ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:34:43
User opened query 'PV Query: Please provide the final event outcome for event, upper respiratory infection , when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:27:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 15:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	30 Apr 2021 16:20:57
Query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' answered with 'updated' (Site from Safety).	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS ADMITTED INTO OSCHNER HOSPITAL; WILL REQUEST MEDICAL RECORDS. MEDICAL RECORDS REVEAL COVID-19 RESULTS WERE NEGATIVE.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Apr 2021 19:34:38
User opened query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' (Site from Safety).	Alexandra Caillouet (b) (4)	29 Apr 2021 19:34:20
User closed query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 11:35:48
Query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' answered with 'updated narrative per query ' (Site from Safety). DataPoint Un-verified.	Amy Thomassie (b) (4)	09 Apr 2021 13:57:57
	Amy Thomassie (b) (4)	09 Apr 2021 13:57:36

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	Amy Thomassie (b) (4)	09 Apr 2021 13:57:36
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL; WILL REQUEST MEDICAL RECORDS. medical records reveal COVID-19 results were negative.' reason for change: Data Entry Error	Amy Thomassie (b) (4)	09 Apr 2021 13:57:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User opened query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:51:46
Query 'query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:51:37
User opened query 'query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:51:34
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per DM CLR: Narrative indicates that the subject tested positive for COVID-19. However, AE term does not reflect this information. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:36:53

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject tested positive for COVID-19. However, AE term does not reflect this information. Please review and update as appropriate or provide clarification.' answered with 'we have requested medical records indicating a positive test multiple times, unable to locate the postitice result' (Site from DM).	Crystal Rowell (b) (4)	24 Mar 2021 14:56:41
User opened query 'Per DM CLR: Narrative indicates that the subject tested positive for COVID-19. However, AE term does not reflect this information. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:06:33
User closed query 'PV Query: Please send a summary of the Urgent care records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 15:40:53
Query 'PV Query: Please send a summary of the Urgent care records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'unable to obtain urgent care records after multiple attempts ' (Site from Safety).	Crystal Rowell (b) (4)	20 Jan 2021 19:58:07
User closed query 'PV Query: Since it is reported that the subject has a positive COVID-19 PCR on 30 Nov 2020, and reported events of upper respiratory infection and shortness of breath, please consider if an additional separate event of COVID-19 should be added. If not, please explain. ' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:44:48
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR A COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:24:11

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR A COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.  ' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 22:36:55
Query 'PV Query: Since it is reported that the subject has a positive COVID-19 PCR on 30 Nov 2020, and reported events of upper respiratory infection and shortness of breath, please consider if an additional separate event of COVID-19 should be added. If not, please explain. ' answered with 'results in ED were negative; subject reported positive result , however there is no record of a positive sample at patient facility visits' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 22:36:49
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR A COLONOSCOPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:56:32
User opened query 'PV Query: Since it is reported that the subject has a positive COVID-19 PCR on 30 Nov 2020, and reported events of upper respiratory infection and shortness of breath, please consider if an additional separate event of COVID-19 should be added. If not, please explain. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:39:24
User opened query 'PV Query: Please send a summary of the Urgent care records with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 21:11:53
User closed query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:27:28

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update case narrative if COVID-19 is negative for both clinic site and hospital. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:27:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:26:45
Query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Augmentin is listed in Con-med as treatment' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	22 Dec 2020 22:25:59
Query 'PV Query: Please update case narrative if COVID-19 is negative for both clinic site and hospital. ' answered with 'medical records from urgent care have been requested- this is where patient states positive test conducted' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	22 Dec 2020 22:24:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'sent with medical records' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	22 Dec 2020 22:23:56
User closed query '(pending on AI #6) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 19:19:53
User opened query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:55:25

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event, shortness of breath, 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. ' canceled (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:55:03
User opened query 'PV Query: Please update case narrative if COVID-19 is negative for both clinic site and hospital. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:53:20
User opened query 'PV Query: Please provide treatment given for the event, shortness of breath, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:52:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:51:24
Query '(pending on AI #6) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records sent' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	21 Dec 2020 18:51:42
User closed query 'PV Query: Is the event a confirmed symptomatic positive COVID-19 case? If so, please consider updating the event term upper respiratory infection to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:03:06
User closed query 'PV Query: Please provide COVID-19 test results on exam conducted on 10 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:02:44
User closed query 'PV Query: Please confirm COVID-19 testing date, test type, and date of positive result on test conducted during pre-colonoscopy work-up.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:02:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:02:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:02:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'covid 19 negative from Hospital PCR swab and research clinic site PCR swab ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:38:35
Query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:38:04
Query 'PV Query: Is the event a confirmed symptomatic positive COVID-19 case? If so, please consider updating the event term upper respiratory infection to COVID-19.' answered with 'updated as Upper respiratory infection ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:36:47
Query 'PV Query: Please provide COVID-19 test results on exam conducted on 10 Dec 2020.' answered with 'results are negative PCR research clinic site illness visit' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:36:19
Query 'PV Query: Please confirm COVID-19 testing date, test type, and date of positive result on test conducted during pre-colonoscopy work-up.' answered with 'Pt was admitted for suspected covid 19 ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:35:34

US3362071

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Is the event a confirmed symptomatic positive COVID-19 case? If so, please consider updating the event term upper respiratory infection to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:28:46
User opened query 'PV Query: Please provide COVID-19 test results on exam conducted on 10 Dec 2020.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:28:37
User opened query 'PV Query: Please confirm COVID-19 testing date, test type, and date of positive result on test conducted during pre-colonoscopy work-up.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:28:29
User opened query '(pending on AI #6) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:28:18
User opened query 'PV Query: Please provide treatment given for the event, upper respiratory infection, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:27:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:27:08
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL; WILL REQUEST MEDICAL RECORDS' reason for change: Data Entry Error	Crystal Rowell (b) (4)	08 Dec 2020 16:02:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL' reason for change: Data Entry Error	Crystal Rowell (b) (4)	08 Dec 2020 16:00:28
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL ON' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 15:26:16
User entered 'Subject went in for a Colonoscopy and was tested for Covid-19 prior to procedure. On the day of the Colonoscopy, subject was having difficulty breathing and a severe cough. He was sent down for a positive Covid-19 result and was admitted into Oschner Hospital on'	(b) (4), (b) (6)	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 15:12:19

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:52:11
User entered 'USA-US112-2020-mRNA-1273-P301000013'	(b) (4), (b) (6)	14 Dec 2020 20:51:59

US3362071

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 18:11:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 18:11:56
Data point term sent to Coder	System	14 Dec 2020 18:10:25
User entered 'Dehydration'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

US3362071

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

US3362071

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:45:27
Query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 22:43:24
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:43:17
User opened query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 17:01:46
User entered '4 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

US3362071

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: As the last dose of study drug was given on 04 Sep 2020 please update the action taken with study drug from none to not applicable for the event, dehydration.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:59:44
Query 'PV Query: As the last dose of study drug was given on 04 Sep 2020 please update the action taken with study drug from none to not applicable for the event, dehydration.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:28:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:28:28
User opened query 'PV Query: As the last dose of study drug was given on 04 Sep 2020 please update the action taken with study drug from none to not applicable for the event, dehydration.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:29:18
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:09:42

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	14 Dec 2020 18:29:00
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 18:29:00
User entered 'subject was admitted with the above Dx. Then on 05DEC2020 discharged to home.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 18:29:00
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 18:09:42
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 18:09:42

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:06:37
User entered 'USA-US112-2020-mRNA-1273-P301000013'	(b) (4), (b) (6)	15 Dec 2020 19:27:52

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:37:59
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:29:34
answered with 'yes, this patient was brought in for an illness visit as soon as site was notified- 12 days later' (Site from DM).		
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	01 Feb 2021 12:29:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:16:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:16:19
Data point term sent to Coder	System	14 Dec 2020 20:14:59
User entered 'SHORTNESS OF BREATH'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 16:50:12
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Negative COVID swab.' (Site from DM).	Alexandra Caillouet (b) (4)	15 Dec 2020 18:52:21
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	15 Dec 2020 18:52:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 18:15:43
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 18:15:41
Query 'Data is required. Please complete.' answered with 'PENDING' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 20:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:14:05
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:30:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide the event end date for the event, shortness of breath (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:01:24
Query 'PV Query: Please provide the event end date for the event, shortness of breath (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.'	(b) (4), (b) (6)	16 Dec 2020 20:33:52
answered with 'updateded' (Site from Safety).		
User entered '5 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:30:57
User opened query 'PV Query: Please provide the event end date for the event, shortness of breath (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)	16 Dec 2020 18:30:05
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	15 Dec 2020 16:52:35
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	15 Dec 2020 16:50:28
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	15 Dec 2020 16:50:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	15 Dec 2020 16:50:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:50:28
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	14 Dec 2020 20:14:05
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Requires inpatient or prolongation System 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).	(b) (4)	15 Dec 2020 16:53:00
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		15 Dec 2020 16:53:00
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		15 Dec 2020 16:52:35
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		15 Dec 2020 16:52:35
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).	System	15 Dec 2020 16:52:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:52:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	15 Dec 2020 16:52:17
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:46:12
Query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 22:43:57
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:43:52
User opened query 'PV Query: It is reported that the subject was admitted to the hospital for upper respiratory infection on 03 Dec 2020, shortness of breath on 04 Dec 2020, and dehydration on 04 Dec 2020. Please consider updating admission dates for shortness of breath and dehydration to date of ER visit 03 Dec 2020. If not, please explain. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:41:38
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:52:17
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:52:17
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:53:00
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:58:58
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Albuterol added.' (Site from DM).	Alexandra Caillouet (b) (4)	25 Mar 2021 18:58:52
User entered '0' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	25 Mar 2021 18:58:43
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:38:32
User closed query 'Per DM CLR: Is this AE Serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:38:32
Query 'Per DM CLR: Is this AE Serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' answered with 'medical records reviewed, noted to have been treated with albuterol- will update conmeds ' (Site from DM).	Crystal Rowell (b) (4)	24 Mar 2021 14:45:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Is this AE Serious? = Yes. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:05:22
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:43:52
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:31:32
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '1' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 18:58:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	13 Jan 2021 16:25:03
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	12 Jan 2021 22:44:02
' answered with 'updated' (Site from DM).		
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 22:43:52
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	11 Jan 2021 04:57:03
' (Site from DM).		
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:31:32
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide the final event outcome for event, shortness of breath, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:01:44
Query 'PV Query: Please provide the final event outcome for event, shortness of breath, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:33:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:30:57
User opened query 'PV Query: Please provide the final event outcome for event, shortness of breath, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:29:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Query 'PV Query: Please provide treatment given for the event, shortness of breath, 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. ' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:13:16
User opened query 'PV Query: Please provide treatment given for the event, shortness of breath, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:56:00
User closed query 'PV Query: Please provide treatment given for the event, shortness of breath, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:01:47
Query 'PV Query: Please provide treatment given for the event, shortness of breath, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 20:34:05

US3362071

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event, shortness of breath, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:30:21
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Dec 2020 16:52:17
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Dec 2020 16:52:17
User entered 'subject was admitted for covid like symptoms' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 16:52:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Dec 2020 16:50:28
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Dec 2020 16:50:28
User entered '0'	System	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:14:05

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 16:53:00

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:33:50
User entered 'USA-US112-2020-mRNA-1273-P301000013'	(b) (4), (b) (6)	15 Jan 2021 12:33:47

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 20:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 20:14:03
Data point term sent to Coder	System	14 Jan 2021 20:13:00
User entered 'Abdominal Pain'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '23 Nov 2020'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '4 Dec 2020'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	14 Jan 2021 20:13:00
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Jan 2021 20:12:21
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed 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).	(b) (4)	14 Jan 2021 20:14:21
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.' answered by data change (Site from System).	System	14 Jan 2021 20:14:21
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).	System	14 Jan 2021 20:13:00
User entered '1' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:13:00
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '3 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:13:00
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:13:00
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:14:21
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:40:42
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	Crystal Rowell (b) (4)	24 Mar 2021 14:24:51
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 07:04:58
	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:22:04
User signature succeeded.	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
Query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' answered with 'updated' (Site from Safety).	Alexandra Caillouet (b) (4)	29 Apr 2021 19:36:28
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS ADMITTED INTO OSCHNER HOSPITAL; THIS IS AN OVERLAPPING SAE WITH SOB AND UPPER RESPIRATORY INFECTION. HOSPITAL RECORDS WERE ALREADY SENT. STILL AWAITING URGENT CARE RECORDS. MEDICAL RECORDS REVEAL COVID-19 RESULTS WERE NEGATIVE.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Apr 2021 19:36:08
User opened query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative. Please remove statement regarding positive test results. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 11:36:15
User closed query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 19:17:47

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' answered with 'updated narrative per query ' (Site from Safety). DataPoint Un-verified.	Amy Thomassie (b) (4)	09 Apr 2021 13:56:00
	(b) (4)	
	Amy Thomassie (b) (4)	09 Apr 2021 13:55:34
	(b) (4)	
Signature has been broken.	Amy Thomassie (b) (4)	09 Apr 2021 13:55:34
	(b) (4)	
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL; THIS IS AN OVERLAPPING SAE WITH SOB AND UPPER RESPIRATORY INFECTION. HOSPITAL RECORDS WERE ALREADY SENT. STILL AWAITING URGENT CARE RECORDS. medical records reveal COVID-19 results were negative.' reason for change: Data Entry Error DataPoint Verified.	Amy Thomassie (b) (4)	09 Apr 2021 13:55:34
	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User opened query 'PV query: Please consider updating the case narrative regarding COVID-19 test results, since previous follow-up indicates COVID-19 test results in the hospital and clinic were negative.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:52:34
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
	(b) (4)	

US3362071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL; This is an overlapping SAE with SOB and Upper respiratory infection. Hospital records were already sent. Still awaiting Urgent Care records.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:15:35
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Jan 2021 20:14:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Jan 2021 20:14:01
User entered 'SUBJECT WENT IN FOR A COLONOSCOPY AND WAS TESTED FOR COVID-19 PRIOR TO PROCEDURE. ON THE DAY OF THE COLONOSCOPY, SUBJECT FELT SOB AND HAD A COUGH WITH FATIGUE AND WEAKNESS. HE WAS SENT DOWN FOR A POSITIVE COVID-19 RESULT AND WAS ADMITTED INTO OSCHNER HOSPITAL; WILL REQUEST MEDICAL RECORDS' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	14 Jan 2021 20:14:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Jan 2021 20:12:21
User entered empty.	Alexandra Caillouet (b) (4)	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 20:12:21

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 20:14:21

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 15:48:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 15:48:38
Data point term sent to Coder	System	06 Feb 2021 17:11:43
Coding entries removed.	Amy Thomassie (b) (4)	06 Feb 2021 17:11:12
User entered 'gastroesophageal reflux disease' reason for change: Data Entry Error	Amy Thomassie (b) (4)	06 Feb 2021 17:11:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 20:29:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Feb 2021 20:29:30
Data point term sent to Coder	System	01 Feb 2021 20:28:55
User entered 'acid reflux'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:42:21
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'corrected ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:04:22
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 14:04:03
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:57:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '03 Dec 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	06 Feb 2021 17:11:12
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	01 Feb 2021 20:28:51
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	01 Feb 2021 20:28:51
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 20:28:51
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	01 Feb 2021 20:28:42
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	01 Feb 2021 20:28:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:28:42
User entered '25 Jan 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 20:28:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:28:30
User entered 'un Jan 2020' (non-conformant).	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:57:06
Query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' answered with 'PI confirmed as NA' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Feb 2021 17:11:20
User opened query 'Per CDM: Please be aware that according to a CRF Completion Guideline, "Not applicable" can be selected only if AE started before the first dose of IP. Please consider selecting related or not related. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:13:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'Per CDM: AE started after the last dose of IP then please consider changing that from "None" to "Not applicable". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:56:45
Query 'Per CDM: AE started after the last dose of IP then please consider changing that from "None" to "Not applicable". Thank you!' answered with 'updated to NA' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Feb 2021 17:11:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	06 Feb 2021 17:11:12
User opened query 'Per CDM: AE started after the last dose of IP then please consider changing that from "None" to "Not applicable". Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:07:18
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

US3362071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 20:28:30

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:15
User entered 'USA-US112-2021-mRNA-1273-P301000013'	System	15 Mar 2021 18:54:44
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 18:54:44

US3362071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic dissection, LLT: Dissecting aneurysm of aorta - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 23:09:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 23:09:51
Data point term sent to Coder	System	12 Mar 2021 20:22:12
User entered 'Dissecting Aorta'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'No (N)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Mar 2021'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 19:40:43
DataPoint Un-verified.	Alexandra Caillouet	29 Apr 2021 19:40:43
	(b) (4)	
Signature has been broken.	Alexandra Caillouet	29 Apr 2021 19:40:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet	29 Apr 2021 19:40:43
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 19:40:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
	(b) (4)	
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
	(b) (4)	
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 15:50:28
	(b) (4)	
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'medical records requested ' (Site from Safety).	Crystal Rowell (b) (4)	24 Mar 2021 13:57:31
	(b) (4)	
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:46:41
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	12 Mar 2021 20:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:00
User signature succeeded.	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' answered with 'Updated' (Site from Safety).	Alexandra Caillouet (b) (4)	29 Apr 2021 19:41:07
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
Signature has been broken.	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
User entered '10 Mar 2021' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 11:20:15
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'I'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '5 Mar 2021'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:54:31
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'medical records requested ' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 13:57:54
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)	22 Mar 2021 13:49:10
User entered '10 Mar 2021'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User closed query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:04:09
Query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	31 Mar 2021 21:56:06
Signature has been broken.	Alexandra Caillouet (b) (4)	31 Mar 2021 21:55:53
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	31 Mar 2021 21:55:53
User opened query 'Per CDM RQ: Please confirm if this information is available and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:01:14
User closed query 'Per CDM: Please keep this query open until there is enough information what to enter. Thank you!' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:01:14
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
Query 'Per CDM: Please keep this query open until there is enough information what to enter. Thank you!' answered with 'medical records requested ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 13:58:04
User opened query 'Per CDM: Please keep this query open until there is enough information what to enter. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:28:43
User closed 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).	(b) (4), (b) (6)	18 Mar 2021 06:28:19
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.' answered with 'Awaiting hospital medical records. Will update AE appropriately once received.' (Site from System).	Alexandra Caillouet (b) (4)	12 Mar 2021 20:24:16

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[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	12 Mar 2021 20:21:59
User entered 'Unknown (UNK)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:57:28
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' answered with 'medical records requested, no surgical intervention, medication list updated ' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 13:58:36
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:47:58
User entered 'I'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:57:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'medical records requested, no surgical intervention, medication list updated ' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	24 Mar 2021 13:58:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:47:36
User entered '0'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Generated On: 09 Jun 2021 17:14:15

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:09
User signature succeeded.	Jordan Whatley (b) (4)	30 Apr 2021 00:06:55
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'updated' (Site from Safety).	Alexandra Caillouet (b) (4)	29 Apr 2021 19:41:32
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
Signature has been broken.	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	29 Apr 2021 19:40:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 11:20:29
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 15:51:47

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:14:15

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'medical records requested, no surgical intervention, medication list updated ' (Site from Safety).	Crystal Rowell (b) (4)	24 Mar 2021 13:58:49
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:47:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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**Generated On: 09 Jun 2021 17:14:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:15
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Unable to obtain cope of medical records. ' (Site from Safety).	Alexandra Caillouet (b) (4)	29 Apr 2021 19:42:14
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:16:00
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)	01 Apr 2021 11:19:57
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:22
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:44:37
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 15:52:03

US3362071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject contacted site to notify of hospital admission on 05Mar2021 for abdominal pain, dx with dissecting aorta, medical mangement with oral medication, no surgery, instructed to follow up with vascular specialist after discharge, records requested.' reason for change: Data Entry Error	Crystal Rowell (b) (4)	24 Mar 2021 14:01:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'medical records requested, no surgical intervention, medication list updated ' (Site from System).	Crystal Rowell (b) (4)	24 Mar 2021 13:59:11
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'medical records requested, no surgical intervention, medication list updated , no covid testing done ' (Site from Safety).	Crystal Rowell (b) (4)	24 Mar 2021 13:59:04
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:46:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Mar 2021 20:21:59
User entered empty.	Alexandra Caillouet (b) (4)	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 20:21:59

**US3362071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 20:21:59

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:14:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:52
User closed query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'No', however, medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:16:28
Query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'No', however, medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' answered with 'data updated "yes" vs "no"' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 16:59:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 16:57:29
User opened query 'Per CDM-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'No', however, medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:32:39
User closed query 'Per CDM re-query: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:42:52
Query 'Per CDM re-query: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'subject entered incorrect response. he did not take a medication to treat pain or fever' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:37:34

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:14:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:34:48
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:34:48
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 21:48:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 21:48:20
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:30:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:48:03

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
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.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:11:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:11:59
Data point term sent to Coder	System	26 Aug 2020 19:49:27
User entered 'LISINOPRIL'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'HYPERTENSION'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '10' reason for change: Data Entry Error		16 Mar 2021 17:42:14
User entered '40'		26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'UN UNK 2015'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:49:13

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:49:13

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:12:25
Data point term sent to Coder	System	26 Aug 2020 19:57:55
User entered 'AMLODIPINE'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'HYPERTENSION'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '10'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'UN UNK 2015'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:57:25

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:57:25

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:12:34
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 18:12:34
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	26 Aug 2020 19:58:57
User entered 'FISH OIL'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 01:59:42
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'will be updated' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:44:17
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 13:17:17
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '1000'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'UN UNK 2015'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:58:14

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 19:58:14

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:51:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:51:40
Data point term sent to Coder	System	14 Dec 2020 20:28:33
Data point term sent to Coder	System	14 Dec 2020 20:25:14
User entered 'SODIUM BICARBONATE'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'PRINCIPAL AE:DEHYDRATION'		14 Dec 2020 20:27:59
reason for change: Data Entry Error		
User entered 'DEHYDRATION'		14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	08 Apr 2021 18:24:37
User entered '650' reason for change: Data Entry Error		29 Jan 2021 18:12:53
User entered '625'		14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '03 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:23:31
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	26 Jan 2021 23:40:02
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	26 Jan 2021 23:39:58
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '5 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet	26 Jan 2021 23:39:58
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered '2'	System	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered '1'	System	14 Dec 2020 20:25:12

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:09
User entered '804 (804)'	System	14 Dec 2020 20:25:12

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:26:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:26:54
Data point term sent to Coder	System	14 Dec 2020 20:26:19
User entered 'VITAMIN D'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'NUTRITIONAL SUPPORT'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '1000'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'IU (IU)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '03 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:26:04

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:26:04

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:28:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:28:51
Data point term sent to Coder	System	22 Dec 2020 22:26:01
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	22 Dec 2020 22:25:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 23:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 23:50:46
Data point term sent to Coder	System	14 Dec 2020 20:28:26
User entered 'AMOXICILLIN CLAVULUNATE'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'AE Upper Respiratory Infection' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	22 Dec 2020 22:25:24
User entered 'PRINICPAL AE: DEHYDRATION'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '500/125'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'three times daily (TID)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '03 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '08 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered '3'	System	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered '1'	System	14 Dec 2020 20:27:37

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:16
User entered '804 (804)'	System	14 Dec 2020 20:27:37

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 23:45:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 23:45:57
Data point term sent to Coder	System	26 Jan 2021 23:44:27
Coding entries removed.	Alexandra Caillouet	26 Jan 2021 23:43:35
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:37:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 18:37:59
	(b) (4)	
Data point term sent to Coder	System	14 Dec 2020 20:29:40
User entered 'DICYCLOMINE'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:20:41
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'update' (Site from DM).	Alexandra Caillouet (b) (4)	26 Jan 2021 23:43:42
User entered 'Abdominal pain' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	26 Jan 2021 23:43:35
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:58:20
User entered 'PRINCIPAL AE; DEHYDRATION'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '10'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'three times daily (TID)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '03 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:20:58
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'Subject prescribed medicine while admitted for dehydration after presenting with abdominal pain and shortness of breath. Given this medicine for abdominal pain. Medicine still ongoing.' (Site from DM).	Alexandra Caillouet (b) (4)	26 Jan 2021 23:45:17
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:57:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 20:29:36

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:29:36

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:29:36

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 17:13:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 17:13:44
Data point term sent to Coder	System	06 Feb 2021 17:13:43
User entered 'protonix'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'gastroesophageal reflux disease'	Amy Thomassie (b) (4) (b) (4)	06 Feb 2021 17:13:21

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '40'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'twice daily (BID)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Amy Thomassie (b) (4) (b) (4)	06 Feb 2021 17:13:21

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '25 Jan 2021'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Amy Thomassie (b) (4)	06 Feb 2021 17:13:21
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Feb 2021 17:13:21

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Feb 2021 17:13:21

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Feb 2021 17:13:21

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:23:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:23:38
Data point term sent to Coder	System	12 Mar 2021 20:18:06
User entered 'Carvedilol'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:17:19

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Dissecting Aorta'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '25'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:17:19

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'twice daily (BID)'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '5 Mar 2021'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	12 Mar 2021 20:17:19
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 20:17:19

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:17:19

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 20:17:19

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:59:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:59:04
Data point term sent to Coder	System	12 Mar 2021 20:20:07
User entered 'Hydralazine'	Alexandra Caillouet (b) (4)	12 Mar 2021 20:19:22

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Dissecting Aorta'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '50'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'three times daily (TID)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '5 Mar 2021'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	12 Mar 2021 20:19:22
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 20:19:22

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 20:19:22

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 20:19:22

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
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)	17 Mar 2021 07:30:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:30:41
	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 21:04:06
User entered 'Aspirin'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'History of Non-STEMI Myocardial Infarct'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '81'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'un UNK 2015'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:03:32
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 21:03:32

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 21:03:32

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:12:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:12:46
Data point term sent to Coder	System	16 Mar 2021 21:05:07
User entered 'Spironolactone'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:04:57

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Systolic Congestive Heart Failure'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:04:57

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '25'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'once daily (QD)'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'un UNK 2016'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	16 Mar 2021 21:04:57
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet (b) (4)	16 Mar 2021 21:04:57

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 21:04:57

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 21:04:57

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 21:04:57

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE HYDROCHLORIDE, PRODUCTSYNONYM: BENTYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:14:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 19:14:29
Data point term sent to Coder	System	25 Mar 2021 18:57:36
User entered 'Bentyl'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Gastroesophageal reflux disease'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '10'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'mg (mg)'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'three times daily (TID)'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Oral (ORAL)'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet (b) (4)	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '3 Dec 2020'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Yes (Y)'	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	25 Mar 2021 18:56:38
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 18:56:38

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 18:56:38

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 19:14:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 19:14:30
Data point term sent to Coder	System	25 Mar 2021 18:58:36
User entered 'Albuterol HFA'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'No (N)'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Shortness of Breath'	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '2'	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'puff (PUFF)'	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	08 Apr 2021 18:24:37
User entered 'four times daily (QID)'	(b) (4), (b) (6)	08 Apr 2021 18:24:37
	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '3 Dec 2020'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:24:37
User entered '0'	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:30:39
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 20:15:25
User entered 'No (N)' reason for change: Data Entry Error		08 Apr 2021 20:15:25
DataPoint Verified.		08 Apr 2021 18:24:37
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		07 Apr 2021 11:15:06
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:15:25
User entered '30 Dec 2020' reason for change: Data Entry Error		08 Apr 2021 20:15:25
DataPoint Verified.		08 Apr 2021 18:24:37
User entered empty.	Alexandra Caillouet (b) (4)	25 Mar 2021 18:57:55

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	08 Apr 2021 18:24:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 18:24:37
	Alexandra Caillouet	25 Mar 2021 18:57:55
	(b) (4)	

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '4'	System	25 Mar 2021 18:57:55

US3362071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '1'	System	25 Mar 2021 18:57:55

**US3362071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:14:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:26
User entered '804 (804)'	System	25 Mar 2021 18:57:55

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:14:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:24:56
User entered 'Yes (Y)' reason for change: Data Entry Error		12 Jan 2021 22:37:10
User entered 'No (N)'		26 Aug 2020 15:23:38

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:25:02
User entered '3 Dec 2020'	(b) (4), (b) (6)	12 Jan 2021 22:37:28

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:25:02
User entered 'colonoscopy'	(b) (4), (b) (6)	12 Jan 2021 22:37:28

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:25:02
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	12 Jan 2021 22:37:28

US3362071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:48:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:25:02
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 22:37:28

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '09/Dec/2020 17:18'	System	09 Dec 2020 22:18:45

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		09 Dec 2020 22:20:50
User entered '1'		09 Dec 2020 22:18:45

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '14/Dec/2020 12:54'	System	14 Dec 2020 20:54:11

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 20:54:59
User entered '1' reason for change: Data Entry Error		14 Dec 2020 20:54:11
User entered '0'		14 Dec 2020 20:53:42

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '15/Dec/2020 14:30'	System	15 Dec 2020 19:30:07

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
User entered '1'		15 Dec 2020 19:30:07

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '17/Dec/2020 10:08'	System	17 Dec 2020 16:08:11

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		04 Jan 2021 19:05:33
User entered 'I'		17 Dec 2020 16:08:11

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '22/Dec/2020 13:21'	System	22 Dec 2020 19:21:16

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		04 Jan 2021 19:05:33
User entered 'I'		22 Dec 2020 19:21:16

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '04/Jan/2021 19:05'	System	04 Jan 2021 19:06:00

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		13 Jan 2021 16:46:35
User entered '1'		04 Jan 2021 19:06:00

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '13/Jan/2021 11:46'	System	13 Jan 2021 16:46:53

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		15 Jan 2021 12:34:00
User entered 'I'		13 Jan 2021 16:46:53

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '15/Jan/2021 07:34'	System	15 Jan 2021 12:34:23

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		26 Mar 2021 13:39:35
User entered 'I'		15 Jan 2021 12:34:23

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (9)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '25/Mar/2021 12:46'	System	25 Mar 2021 16:46:43

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		26 Mar 2021 13:39:35
User entered 'I'		25 Mar 2021 16:46:43

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (10)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:12:22
User entered '26/Mar/2021 08:39'	System	26 Mar 2021 13:39:59

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:18:22
DataPoint Verified.		08 Apr 2021 18:12:22
User entered 'I'		26 Mar 2021 13:39:59

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (11)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
User entered '09/Apr/2021 14:18'	(b) (4) System	09 Apr 2021 19:19:09

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:14:15

**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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:22:32
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 19:19:09

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.		17 Dec 2020 16:07:43
Un-reviewed for Safety.		15 Dec 2020 19:29:42
Reviewed for Safety.		09 Dec 2020 22:18:35
User entered 'USA-US112-2020-MRNA-1273-P301000013'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Yes (Y)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'No (N)'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Jordan'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'Whatley'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '5326 O'donovan dr'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered 'baton rouge'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:18:35
User entered '70808'	System	09 Dec 2020 22:18:22

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:12:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 22:20:50
User entered 'US'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	30 Apr 2021 16:24:02
User entered '11'	System	09 Apr 2021 19:19:09
User entered '10'	System	26 Mar 2021 13:39:59
User entered '9'	System	25 Mar 2021 16:46:43
User entered '8'	System	15 Jan 2021 12:34:23
User entered '7'	System	13 Jan 2021 16:46:53
User entered '6'	System	04 Jan 2021 19:06:00
User entered '5'	System	22 Dec 2020 19:21:16
User entered '4'	System	17 Dec 2020 16:08:11
User entered '3'	System	15 Dec 2020 19:30:07
User entered '2'	System	14 Dec 2020 20:54:11
User entered '1'	System	09 Dec 2020 22:18:45

**US3362071**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (12)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	01 May 2021 03:16:13
User entered '30/Apr/2021 12:23'	(b) (4) System	30 Apr 2021 16:24:02

US3362071

Folder: SAE USA-US112-2020-MRNA-1273-P301000013

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	01 May 2021 03:16:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:24:02

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered		
'USA-US112-2021-MRNA-1273-P301000013'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Jordan'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Whatley'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '5326 O'donovan dr'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'baton rouge'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '70808'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'US'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 16:58:56
User entered '3'	System	01 Apr 2021 15:16:19
User entered '2'	System	25 Mar 2021 15:59:54
User entered '1'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered		
'USA-US112-2021-MRNA-1273-P301000013'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Jordan'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Whatley'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '5326 O'donovan dr'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'baton rouge'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '70808'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'US'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 16:58:56
User entered '3'	System	01 Apr 2021 15:16:19
User entered '2'	System	25 Mar 2021 15:59:54
User entered '1'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered '15/Mar/2021 18:55'	System	15 Mar 2021 18:55:58

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:15

**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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered		
'USA-US112-2021-MRNA-1273-P301000013'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Jordan'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Whatley'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '5326 O'donovan dr'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'baton rouge'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '70808'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'US'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 16:58:56
User entered '3'	System	01 Apr 2021 15:16:19
User entered '2'	System	25 Mar 2021 15:59:54
User entered '1'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered '25/Mar/2021 11:59'	System	25 Mar 2021 15:59:54

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:15

**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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 15:59:54

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered		
'USA-US112-2021-MRNA-1273-P301000013'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Jordan'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Whatley'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '5326 O'donovan dr'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'baton rouge'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '70808'	System	15 Mar 2021 18:54:44

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'US'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 16:58:56
User entered '3'	System	01 Apr 2021 15:16:19
User entered '2'	System	25 Mar 2021 15:59:54
User entered '1'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered '01/Apr/2021 08:16'	System	01 Apr 2021 15:16:19

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:15

**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)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 15:16:19

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered		
'USA-US112-2021-MRNA-1273-P301000013'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Yes (Y)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'No (N)'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Jordan'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'Whatley'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '5326 O'donovan dr'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered 'baton rouge'	System	15 Mar 2021 18:54:44

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:13:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 18:55:38
User entered '70808'	System	15 Mar 2021 18:54:44

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:15

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 16:58:30
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:05:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:13:09
User entered 'US'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:14:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 16:58:56
User entered '3'	System	01 Apr 2021 15:16:19
User entered '2'	System	25 Mar 2021 15:59:54
User entered '1'	System	15 Mar 2021 18:55:58

**US3362071**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:14:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	01 May 2021 03:16:13
User entered '30/Apr/2021 12:58'	(b) (4) System	30 Apr 2021 16:58:56

US3362071

Folder: SAE USA-US112-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:15

**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.	Jordan Whatley (b) (4)	01 May 2021 03:16:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:58:56