

US3062167 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:59:37

All time stamps listed in this document are displayed in GMT

US3062167

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:41:44

Generated On: 09 Jun 2021 14:59:37

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Participant ID

US3062167

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

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US3062167

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Date of Informed Consent (*dd MMM yyyy*) 8 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:40:04

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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) 15 Feb 2021 15:40:04

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Condition	TYPE 2 DIABETES MELLITUS
Start date (dd MMM yyyy)	01 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Condition	OSTEOARTHRITIS-BILATERAL HANDS, SHOULDERS
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:18 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 08:18
Height ( <i>xxx.x</i> )	178.0 cm
Weight ( <i>xxx.x</i> )	107.4 kg
BMI ( <i>xxx.x</i> )	33.89724 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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) 15 Feb 2021 15:40:04

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:40:04

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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) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 143375

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:40:04

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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)	08 AUG 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 08:18
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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)	08 AUG 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 10:53
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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) 8 AUG 2020

What was the treatment time? (00:00-23:59) 10:22 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 10:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 AUG 2020

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

08 AUG 2020 09:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:02	08 AUG 2020 09:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

08 AUG 2020 11:09

PC Open Date & Time

08 AUG 2020 10:42

PC Close Date & Time

08 AUG 2020 13:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	08 AUG 2020 21:21
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 18:28

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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 19:11

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

13 AUG 2020 19:19

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**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

96.0 °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

14 AUG 2020 22:38

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 11:09

PC Open Date & Time

08 AUG 2020 10:42

PC Close Date & Time

08 AUG 2020 13:12

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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

08 AUG 2020 21:22

PC Open Date & Time

08 AUG 2020 14:07

PC Close Date & Time

09 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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

09 AUG 2020 18:29

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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 19:11

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

11 AUG 2020 18:58

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

12 AUG 2020 20:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**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

13 AUG 2020 19:20

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 22:38

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 11:10
PC Open Date & Time	08 AUG 2020 10:42
PC Close Date & Time	08 AUG 2020 13:12

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 21:23
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

44 of 3010

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:29
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

46 of 3010

EAB) (1725)

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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



US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:58
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:46
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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 ☒

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:20
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 22:39
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59



US3062167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	07:36 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 07:36
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG



US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 09:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3062167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3062167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 09:08 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 09:08

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

US3062167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	8 SEP 2020
-------------------------------	------------

Collection time (00:00-23:59)	07:52 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 SEP 2020 07:52
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US3062167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:53	8 SEP 2020 07:53
Nasopharyngeal Swab 2	No		

US3062167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 09:43

PC Open Date & Time

08 SEP 2020 09:28

PC Close Date & Time

08 SEP 2020 11:58

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 08 SEP 2020 12:53

PC Close Date & Time 09 SEP 2020 11:59



US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:21

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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**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

95.6 °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

15 SEP 2020 00:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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

08 SEP 2020 09:43

PC Open Date & Time

08 SEP 2020 09:28

PC Close Date & Time

08 SEP 2020 11:58

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:53

PC Close Date & Time

09 SEP 2020 11:59



US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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

09 SEP 2020 20:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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 SEP 2020 20:07

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

11 SEP 2020 19:22

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

12 SEP 2020 15:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**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

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 00:48

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:44
PC Open Date & Time	08 SEP 2020 09:28
PC Close Date & Time	08 SEP 2020 11:58



US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:53

PC Close Date & Time

09 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:16
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:08
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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



US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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 ☒

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

98 of 3010

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 3010

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:03

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3062167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:00 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 08:00
Temperature ( <i>xxx.x</i> )	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062167

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

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.*

US3062167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 OCT 2020

Collection time (00:00-23:59)

08:08 (24 HR)

Collection date and time (derived)

10 OCT 2020 08:08



US3062167

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:40:04

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 64

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

No ☒

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

10 OCT 2020 08:19:40

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

17 OCT 2020 08:17:48

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 OCT 2020 21:17:32
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 NOV 2020 13:00:23
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 06:13:53

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

19 NOV 2020 00:01:48

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 10:54:28

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59



US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 08:34:54

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 09:01:54

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 DEC 2020 11:36:12
Patient Cloud Open Date & Time	14 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	122 of 3010

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 07:19:23

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 07:22:13

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

04 JAN 2021 00:12:23

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 09:36:33

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59



US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

27 JAN 2021 00:03:16

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 06:58:13

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 07:01:33

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 05:48:18

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 06:11:13

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

01 MAR 2021 09:01:48

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59



US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 06:27:07

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 14:56:48

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

22 MAR 2021 08:37:14

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 07:01:12

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 06:48:09

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 00:01:54

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

19 APR 2021 00:01:59

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 06:27:51

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59



US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 07:00:14

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 327

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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30 JUL 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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10 SEP 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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15 APR 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 APR 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐ 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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 712

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐  
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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3062167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	10 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59
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**US3062167**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 14:59:37**

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 15:05:03



US3062167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:00:38

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

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	VISIT4
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US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3062167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 FEB 2021

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

26 FEB 2021 15:05

US3062167

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:21:38

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:21:38

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3062167**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

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*



**US3062167**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Date of Contact	10 DEC 2020
Time of Contact	09:25
Date and Time of Contact (derived)	10 DEC 2020 09:25
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>

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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"/>

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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"/>

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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"/>

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	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	99 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	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	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	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	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	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	99 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	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	99 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	16 DEC 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	18 DEC 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	19 DEC 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	20 DEC 2020
------	-------------

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

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

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	21 DEC 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Symptom Day

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Date	23 DEC 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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) 1

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3062167

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	16 DEC 2020
Day 9	Yes	18 DEC 2020
Day 14	No	
Day 21	Yes	30 DEC 2020
Day 28	Yes	13 JAN 2021

US3062167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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

Visit date (dd MMM yyyy)	10 DEC 2020
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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	SICKD1
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US3062167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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> )	14:15 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 14:15
Height ( <i>xxx.x</i> )	178.0 cm
Weight ( <i>xxx.x</i> )	107.4 kg
Temperature ( <i>xxx.x</i> )	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	52 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062167

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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.*

US3062167

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020



US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	SICKD28
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US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 16:05
Height (xxx.x)	178.0 cm
Weight (xxx.x)	107.4 kg
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3062167

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3062167

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3062167

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Height	180.3 cm
Weight	112.8 kg
BMI (xxx.x)	34.69905

US3062167

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Height	180.3 cm
Weight	112.8 kg
BMI (xxx.x)	34.69905
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 08:19
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG



US3062167

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Height	180.3 cm
Weight	112.8 kg
BMI (xxx.x)	34.69905
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 10:31
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3062167

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3062167

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

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

Treatment Date and Time (derived) 26 JAN 2021 09:59

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

US3062167

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

26 JAN 2021 08:25

US3062167

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00 - 23:59)	08:27
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Collection Date and Time (derived)	26 JAN 2021 08:27
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US3062167

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3062167

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

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	OLD29
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US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:37
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062167

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3062167

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 16:05

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

US3062167

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062167

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3062167

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3062167

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:21:38

Generated On: 09 Jun 2021 14:59:37

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

Visit date (dd MMM yyyy)	2 APR 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	OLD57
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US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:21:38

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 APR 2021
Time of assessment (00:00-23:59)	16:03 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 16:03
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:21:38

Generated On: 09 Jun 2021 14:59:37

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.*

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:21:37

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	2 APR 2021
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Collection time (00:00-23:59)	16:06 (24 HR)
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Collection date and time (derived)	2 APR 2021 16:06
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US3062167

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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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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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

AEID	USA-US090-2020-MRNA-1273-P30 1000007
Adverse event	PROSTATE CANCER
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)	16 OCT 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)	8 JAN 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 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	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 (1)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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SUBJECT REPORTED THAT HE HAD A PROSTATE BIOPSY. THE RESULTS OF THE BIOPSY WERE GIVEN TO THE SUBJECT THIS WEEK. SUBJECT HAS PROSTATE CANCER. HE REPORTS THAT HE IS SCHEDULED FOR PROSTATECTOMY ON 12/14/2020. RELEASE OF RECORDS MAILED TO SUBJECT FOR SIGNATURE. UPDATE 11/25/2020 - SUBJECT HAD PSA LEVEL ON 8/10/2020. PSA WAS 1.6 NG/ML WITH A REFERENCE RANGE OF 0.0-4.0. SUBJECT WAS REFERRED TO UROLOGIST FOR PROSTATE NODULE. SUBJECT REPORTS NO FAMILY HISTORY OF PROSTATE CANCER. SUBJECT HAD A PROSTATE BIOPSY ON 10/16/2020 WITH PATHOLOGY THAT CONFIRMED A DIAGNOSIS OF PROSTATE CANCER. HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. SUBJECT WILL BE HAVING A ROBOTIC ASSISTED LAPROSCOPIC RADICAL PROSTATECTOMY IN DECEMBER 2020. SUBJECT HAD FOLLOW UP VISIT AT



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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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STUDY SITE FOLLOWING A  
COVID ILLNESS VISIT. AT  
FOLLOW UP VISIT SUBJECT  
NOTIFIED STAFF OF  
PROSTATECTOMY THAT TOOK  
PLACE ON 1/8/2021. STAFF  
TOOK DOWN RELEVANT  
INFORMATION. SUBJECT HAD  
PREVIOUSLY SIGNED RELEASE  
OF RECORDS FORM. RELEASE  
OF RECORDS FAXED.

---

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)	

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US3062167

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

AEID	USA-US090-2020-MRNA-1273-P30 1000014
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	08 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)	23 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 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 (2)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

AEID	
Adverse event	ERECTION DYSFUNCTION
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)	20 NOV 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

AEID	
Adverse event	POST OPERATIVE PAIN GENERALIZED
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)	9 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 21:00:37

Generated On: 09 Jun 2021 14:59:37

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 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	
SUBJECT HAD A PROSTATECTOMY, PAIN FOLLOWING OPERATION.	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

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

Yes ☒

No ☐

---

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

---



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS- BILATERAL  
HANDS, SHOULDERS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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 2017	
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"/>

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES MELLITUS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 MAY 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 (4)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication SILDENAFIL

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)		08 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)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication MUCINEX

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)		08 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)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication SUDAFED PE (PHENYLEPHRINE)

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)		08 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) 22 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN  
GENERALIZED

Dose per administration 5/325

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)	9 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication POST OPERATIVE PAIN  
GENERALIZED

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)		11 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication ANCEF

Prophylaxis Yes ☒  
No ☐

Indication INFECTION PROPHYLAXIS

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  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 8 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication	HEPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DEEP VEIN THROMBOSIS PROPHYLAXIS
Dose per administration	5000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	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)		8 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication CEPHALEXIN

Prophylaxis Yes ☒  
No ☐

Indication INFECTION PROPHYLAXIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 JAN 2021		
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 (13)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

Name of Medication CIALIS

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 15:53:26

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:41:45

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 OCT 2020	PROSTATE BIOPSY	Adverse Event	
8 JAN 2021	ROBOTIC ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY	Adverse Event	
8 JAN 2021	BILATERAL PELVIC LYMPHADENECTOMY	Adverse Event	
8 JAN 2021	SUPRAPUBIC TUBE PLACEMENT	Adverse Event	
10 AUG 2020	PSA LEVEL	Diagnostic	
16 OCT 2020	TRANSRECTAL ULTRASOUND OF THE PROSTATE	Adverse Event	

US3062167

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:37

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 14:59:37

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 ☐

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Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/NOV/2020 18:42
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



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/NOV/2020 20:38
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/DEC/2020 13:04
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/JAN/2021 08:53
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/MAR/2021 14:21
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 20:41:46

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/MAR/2021 14:21
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/JAN/2021 21:32
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

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:41:47

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US090-2020-MRNA-1273-P301000014
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/MAR/2021 15:07
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

US3062167 (Prod: Alliance for Multispecialty Research, LLC)

**US3062167**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:59:37**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'US3062167'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:31:21

**US3062167**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:35:57
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:31:22

**US3062167**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:35:57

**US3062167**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'SCRN'	System	08 Aug 2020 15:35:57



**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:31:23

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '56'	Colton King (b) (4)	10 Aug 2020 13:40:57
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'YEARS'	System	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '56'	System	08 Aug 2020 15:36:07

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Male (M)'	Colton King (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Colton King (b) (4)	10 Aug 2020 13:40:57
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'I'	Colton King (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:57



**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:57
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:40:57

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '8 Aug 2020'	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:36:07



**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'Aug 2020'	System	08 Aug 2020 15:36:07

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '2020'	System	08 Aug 2020 15:36:07

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Amendment 1 (1)'	Riley King (b) (4)	08 Aug 2020 15:36:07
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:36:07
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:36:07

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:36:07

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	08 Aug 2020 15:36:07
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:31:22



**US3062167**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'I'	System	08 Aug 2020 15:36:12

**US3062167**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 14:59:37**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:36:12
	(b) (4)	

US3062167

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:59:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:37:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 13:37:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	10 Aug 2020 13:37:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:37:31
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:37:31
	(b) (4)	

US3062167

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User closed query 'Per MM: please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:36:28
Query 'Per MM: please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment. ' answered with 'per patient, not changes 3 months prior to study start' (Site from DM).	marissa Mueller (b) (4)	15 Oct 2020 15:18:16
	(b) (4)	
User opened query 'Per MM: please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:29:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 13:39:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 13:39:16
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 13:38:56
User entered 'Type 2 Diabetes Mellitus'	Colton King (b) (4)	10 Aug 2020 13:38:12
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '01 May 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Oct 2020 15:17:59
	(b) (4)	
User entered 'un May 2020'	Colton King (b) (4)	10 Aug 2020 13:38:12
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:38:12



**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'May 2020'	System	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '2020'	System	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:38:12

**US3062167**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:38:12

US3062167

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 13:37:41
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 13:37:41
User closed query 'Per DM CLR: Please review Condition and please update to specify the location of Osteoarthritis. Please update and if applicable, reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:53:19
Data point term sent to Coder	System	09 Sep 2020 14:56:11
Query 'Per DM CLR: Please review Condition and please update to specify the location of Osteoarthritis. Please update and if applicable, reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated per source ' (Site from DM).	marissa Mueller (b) (4)	09 Sep 2020 14:56:01
Coding entries removed.	marissa Mueller (b) (4)	09 Sep 2020 14:55:52
User entered 'OSTEOARTHRITIS-bilateral hands, shoulders' reason for change: Data Entry Error	marissa Mueller (b) (4)	09 Sep 2020 14:55:52
User opened query 'Per DM CLR: Please review Condition and please update to specify the location of Osteoarthritis. Please update and if applicable, reconcile with AE/CM eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 03:17:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 13:39:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 13:39:16

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 13:38:57
User entered 'Osteoarthritis'	Colton King (b) (4)	10 Aug 2020 13:38:48
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'un UNK 2012'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:38:48



**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:38:48
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'Jan 2012'	System	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '2012'	System	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:38:48

**US3062167**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:38:48



US3062167

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 13:41:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 13:41:15
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 13:40:58
User entered 'Insomnia'	Colton King (b) (4)	10 Aug 2020 13:40:28
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'un UNK 2010'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'Jan 2010'	System	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '2010'	System	10 Aug 2020 13:40:28



**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered empty.	System	10 Aug 2020 13:40:28

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:43:44

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08 Aug 2020'	Colton King (b) (4)	10 Aug 2020 13:43:44

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08:18'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:43:44

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered '08 Aug 2020 08:18'	System	10 Aug 2020 13:43:44

US3062167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '178.0' cm	(b) (4) Colton King (b) (4)	10 Aug 2020 13:43:44
DataPoint set to visible.	(b) (4) System	08 Aug 2020 15:36:12

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '107.4' kg	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	
DataPoint set to visible.	System	08 Aug 2020 15:36:12



**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
Amendment Manager: User entered '33.89724'	System	16 Sep 2020 23:48:32
User entered '33.9'	System	10 Aug 2020 13:43:44
DataPoint set to visible.	System	08 Aug 2020 15:36:12

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'kg/m2'	System	10 Aug 2020 13:43:44
DataPoint set to visible.	System	08 Aug 2020 15:36:12

US3062167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
User entered '98.0' F	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:43:44

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
User entered '54'	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'bpm'	System	10 Aug 2020 13:43:44

US3062167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
User entered '16'	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	



**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'breaths/min'	System	10 Aug 2020 13:43:44

US3062167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
User entered '129'	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'mmHg'	System	10 Aug 2020 13:43:44

US3062167

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:39:55
User entered '87'	Colton King (b) (4)	10 Aug 2020 13:43:44
	(b) (4)	

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User entered 'mmHg'	System	10 Aug 2020 13:43:44

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02

**US3062167**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02

**US3062167**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:15
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:44:04
	(b) (4)	



US3062167

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	11 Sep 2020 13:02:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 14:20:02
User entered '08 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:15
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:44:04

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14

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Folder: Screening

Form: Risk of Exposure

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:45:14

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:45:14

US3062167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14

US3062167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

[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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:45:14

US3062167

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

**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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14



US3062167

Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

**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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14



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Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14

US3062167

Folder: Screening

Form: Risk of Exposure

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**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

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)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'I'	Colton King (b) (4)	10 Aug 2020 13:45:14
	(b) (4)	

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:20:02
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:45:14

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:36:36
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Aug 2020'	Riley King (b) (4)	08 Aug 2020 15:36:36
	(b) (4)	



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Clinic (Clinic)'	Riley King (b) (4)	08 Aug 2020 15:36:36
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'VISIT1'	System	08 Aug 2020 15:36:36

US3062167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:25

US3062167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:03:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:03:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 14:55:25
User entered '143375' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:25

US3062167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:25

US3062167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	08 Aug 2020 15:36:59
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:36:59

US3062167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	08 Aug 2020 15:36:59
	(b) (4)	



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:36:59
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	08 Aug 2020 15:36:59
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '178.0' cm	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '107.4' kg	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '178.0' cm	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '107.4' kg	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:48:05



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08 Aug 2020'	(b) (4) Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08:18'	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered '08 Aug 2020 08:18'	System	10 Aug 2020 13:48:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '98.0' F	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '54'	Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'bpm'	System	10 Aug 2020 13:48:05



US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '16'	Colton King (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'breaths/min'	System	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '129'	Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'mmHg'	System	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '87'	Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'mmHg'	System	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '178.0' cm	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:05
User entered '107.4' kg	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '08 Aug 2020'	Colton King (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 07:45:43
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Correct per protocol' (Site from System).	Colton King (b) (4)	10 Aug 2020 13:48:25
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	10 Aug 2020 13:48:05
User entered '10:53'	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered '08 Aug 2020 10:53'	System	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 09:55:01
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	marissa Mueller (b) (4)	22 Sep 2020 00:12:07
answered with 'NCS' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:48:32
User entered '96.6' F	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Oral (Oral)'	Colton King (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:48:05



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '51'	Colton King (b) (4)	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'bpm'	System	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '16'	Colton King (b) (4)	10 Aug 2020 13:48:05

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'breaths/min'	System	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '127'	Colton King (b) (4)	10 Aug 2020 13:48:05

US3062167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'mmHg'	System	10 Aug 2020 13:48:05

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '74'	Colton King (b) (4)	10 Aug 2020 13:48:05
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'mmHg'	System	10 Aug 2020 13:48:05



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:23
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:48:54
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	24 Aug 2020 23:40:23
	(b) (4)	
User entered '08 Aug 2020'	Colton King (b) (4)	10 Aug 2020 13:48:54
	(b) (4)	

US3062167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	08 Aug 2020 15:37:23
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:37:23

US3062167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	08 Aug 2020 15:37:23

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Aug 2020'	Riley King (b) (4)	08 Aug 2020 15:37:23
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '10:22'	Riley King (b) (4)	08 Aug 2020 15:37:23
	(b) (4)	



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered '8 Aug 2020 10:22'	System	08 Aug 2020 15:37:23

US3062167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Riley King (b) (4)	08 Aug 2020 15:37:23
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'ONCE'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 15:37:23

US3062167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:50:12
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '08 Aug 2020'	Colton King (b) (4)	10 Aug 2020 13:50:12
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '09:00'	(b) (4) Colton King (b) (4)	10 Aug 2020 13:50:12

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered '08 Aug 2020 09:00'	System	10 Aug 2020 13:50:12



US3062167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '08 Aug 2020'	Colton King (b) (4)	10 Aug 2020 13:50:29
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	10 Aug 2020 13:50:29

US3062167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:50:29
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '09:02'	Colton King (b) (4)	10 Aug 2020 13:50:29
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered '08 Aug 2020 09:02'	System	10 Aug 2020 13:50:29

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4)	10 Aug 2020 13:50:29

US3062167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:50:29
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	10 Aug 2020 13:50:29



**US3062167**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered empty.	System	10 Aug 2020 13:50:29

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:50:44
	(b) (4)	

**US3062167**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'I'	System	10 Aug 2020 13:50:44

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:08:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7d3bf45f-76d8-4cf2-82fe-0833e74190b4'	System	08 Aug 2020 16:09:11
User entered 'Yes (Y)'	System	08 Aug 2020 16:09:11

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:08:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7d3bf45f-76d8-4cf2-82fe-0833e74190b4'	System	08 Aug 2020 16:09:11
User entered '96.6'	System	08 Aug 2020 16:09:11

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:08:58', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7d3bf45f-76d8-4cf2-82fe-0833e74190b4'	System	08 Aug 2020 16:09:11
User entered 'No (N)'	System	08 Aug 2020 16:09:11

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7d3bf45f-76d8-4cf2-82fe-0833e74190b4'	System	08 Aug 2020 16:09:11
User entered '08 Aug 2020 11:09'	System	08 Aug 2020 16:09:11



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:20:30', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b46ec8a9-bef1-49a2-940d-fa35ad13ae51'	System	09 Aug 2020 02:21:38
User entered 'Yes (Y)'	System	09 Aug 2020 02:21:38

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:21:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b46ec8a9-bef1-49a2-940d-fa35ad13ae51'	System	09 Aug 2020 02:21:38
User entered '96.3'	System	09 Aug 2020 02:21:38

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:21:28', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b46ec8a9-bef1-49a2-940d-fa35ad13ae51'	System	09 Aug 2020 02:21:38
User entered 'No (N)'	System	09 Aug 2020 02:21:38

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:21:35', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b46ec8a9-bef1-49a2-940d-fa35ad13ae51'	System	09 Aug 2020 02:21:38
User entered '08 Aug 2020 21:21'	System	09 Aug 2020 02:21:38

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 2'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:27:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd51f247d-9377-4e03-b6d9-9201670479b5'	System	09 Aug 2020 23:28:42
User entered 'Yes (Y)'	System	09 Aug 2020 23:28:42

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd51f247d-9377-4e03-b6d9-9201670479b5'	System	09 Aug 2020 23:28:42
User entered '97.0'	System	09 Aug 2020 23:28:42

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd51f247d-9377-4e03-b6d9-9201670479b5'	System	09 Aug 2020 23:28:42
User entered 'No (N)'	System	09 Aug 2020 23:28:42

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:38', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd51f247d-9377-4e03-b6d9-9201670479b5'	System	09 Aug 2020 23:28:42
User entered '09 Aug 2020 18:28'	System	09 Aug 2020 23:28:42

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:37:23



US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 3'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:10:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b7d732fb-3881-47c6-9e3c-e8b248bb0854'	System	11 Aug 2020 00:11:06
User entered 'Yes (Y)'	System	11 Aug 2020 00:11:06

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:10:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b7d732fb-3881-47c6-9e3c-e8b248bb0854'	System	11 Aug 2020 00:11:06
User entered '98.0'	System	11 Aug 2020 00:11:06

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:10:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b7d732fb-3881-47c6-9e3c-e8b248bb0854'	System	11 Aug 2020 00:11:06
User entered 'No (N)'	System	11 Aug 2020 00:11:06

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b7d732fb-3881-47c6-9e3c-e8b248bb0854'	System	11 Aug 2020 00:11:06
User entered '10 Aug 2020 19:11'	System	11 Aug 2020 00:11:06

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 4'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:56:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1b52935c-7a57-47c8-b913-30215848d0b3'	System	11 Aug 2020 23:57:53
User entered 'Yes (Y)'	System	11 Aug 2020 23:57:53

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:57:39', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1b52935c-7a57-47c8-b913-30215848d0b3'	System	11 Aug 2020 23:57:53
User entered '98.1'	System	11 Aug 2020 23:57:53

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:57:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1b52935c-7a57-47c8-b913-30215848d0b3'	System	11 Aug 2020 23:57:53
User entered 'No (N)'	System	11 Aug 2020 23:57:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:57:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1b52935c-7a57-47c8-b913-30215848d0b3'	System	11 Aug 2020 23:57:53
User entered '11 Aug 2020 18:57'	System	11 Aug 2020 23:57:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 5'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:43:53', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'fd30e2aa-8623-4484-834a-ade9145b5115'	System	13 Aug 2020 01:45:36
User entered 'Yes (Y)'	System	13 Aug 2020 01:45:36



US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'fd30e2aa-8623-4484-834a-ade9145b5115'	System	13 Aug 2020 01:45:36
User entered '97.2'	System	13 Aug 2020 01:45:36

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:25', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'fd30e2aa-8623-4484-834a-ade9145b5115'	System	13 Aug 2020 01:45:36
User entered 'No (N)'	System	13 Aug 2020 01:45:36

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'fd30e2aa-8623-4484-834a-ade9145b5115'	System	13 Aug 2020 01:45:36
User entered '12 Aug 2020 20:45'	System	13 Aug 2020 01:45:36

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 6'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:18:37', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '335841d4-850c-4303-941e-60056da2a754'	System	14 Aug 2020 00:19:53
User entered 'Yes (Y)'	System	14 Aug 2020 00:19:53

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:19:37', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '335841d4-850c-4303-941e-60056da2a754'	System	14 Aug 2020 00:19:53
User entered '97.0'	System	14 Aug 2020 00:19:53



US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:19:44', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '335841d4-850c-4303-941e-60056da2a754'	System	14 Aug 2020 00:19:53
User entered 'No (N)'	System	14 Aug 2020 00:19:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:19:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '335841d4-850c-4303-941e-60056da2a754'	System	14 Aug 2020 00:19:53
User entered '13 Aug 2020 19:19'	System	14 Aug 2020 00:19:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 7'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:37:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '61db35b1-85bd-4786-96f1-59f26f767cf7'	System	15 Aug 2020 03:38:33
User entered 'Yes (Y)'	System	15 Aug 2020 03:38:33

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:22', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '61db35b1-85bd-4786-96f1-59f26f767cf7'	System	15 Aug 2020 03:38:33
User entered '96.0'	System	15 Aug 2020 03:38:33

US3062167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '61db35b1-85bd-4786-96f1-59f26f767cf7'	System	15 Aug 2020 03:38:33
User entered 'No (N)'	System	15 Aug 2020 03:38:33



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '61db35b1-85bd-4786-96f1-59f26f767cf7'	System	15 Aug 2020 03:38:33
User entered '14 Aug 2020 22:38'	System	15 Aug 2020 03:38:33

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a89659b0-7e03-4be8-a514-3bbad40070cf'	System	08 Aug 2020 16:09:57
User entered 'None (1)'	System	08 Aug 2020 16:09:57

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a89659b0-7e03-4be8-a514-3bbad40070cf'	System	08 Aug 2020 16:09:57
User entered 'No (N)'	System	08 Aug 2020 16:09:57

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a89659b0-7e03-4be8-a514-3bbad40070cf'	System	08 Aug 2020 16:09:57
User entered 'No (N)'	System	08 Aug 2020 16:09:57

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a89659b0-7e03-4be8-a514-3bbad40070cf'	System	08 Aug 2020 16:09:57
User entered 'None (1)'	System	08 Aug 2020 16:09:57



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:52', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a89659b0-7e03-4be8-a514-3bbad40070cf'	System	08 Aug 2020 16:09:57
User entered '08 Aug 2020 11:09'	System	08 Aug 2020 16:09:57

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:21:44', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b168f4cb-e683-46f9-922a-7af23e063aa2'	System	09 Aug 2020 02:22:28
User entered 'None (1)'	System	09 Aug 2020 02:22:28

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:21:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b168f4cb-e683-46f9-922a-7af23e063aa2'	System	09 Aug 2020 02:22:28
User entered 'No (N)'	System	09 Aug 2020 02:22:28

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:05', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b168f4cb-e683-46f9-922a-7af23e063aa2'	System	09 Aug 2020 02:22:28
User entered 'No (N)'	System	09 Aug 2020 02:22:28

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b168f4cb-e683-46f9-922a-7af23e063aa2'	System	09 Aug 2020 02:22:28
User entered 'None (1)'	System	09 Aug 2020 02:22:28



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b168f4cb-e683-46f9-922a-7af23e063aa2'	System	09 Aug 2020 02:22:28
User entered '08 Aug 2020 21:22'	System	09 Aug 2020 02:22:28

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 2'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '100b2c7c-ca14-4c40-957b-84014598ff60'	System	09 Aug 2020 23:29:15
User entered 'None (1)'	System	09 Aug 2020 23:29:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:52', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '100b2c7c-ca14-4c40-957b-84014598ff60'	System	09 Aug 2020 23:29:15
User entered 'No (N)'	System	09 Aug 2020 23:29:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:28:57', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '100b2c7c-ca14-4c40-957b-84014598ff60'	System	09 Aug 2020 23:29:15
User entered 'No (N)'	System	09 Aug 2020 23:29:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '100b2c7c-ca14-4c40-957b-84014598ff60'	System	09 Aug 2020 23:29:15
User entered 'None (1)'	System	09 Aug 2020 23:29:15



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:12', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '100b2c7c-ca14-4c40-957b-84014598ff60'	System	09 Aug 2020 23:29:15
User entered '09 Aug 2020 18:29'	System	09 Aug 2020 23:29:15

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 3'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c3f20b83-6287-4a42-8219-396353ebab4f'	System	11 Aug 2020 00:12:00
User entered 'None (1)'	System	11 Aug 2020 00:12:00

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:31', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c3f20b83-6287-4a42-8219-396353ebab4f'	System	11 Aug 2020 00:12:00
User entered 'No (N)'	System	11 Aug 2020 00:12:00

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c3f20b83-6287-4a42-8219-396353ebab4f'	System	11 Aug 2020 00:12:00
User entered 'No (N)'	System	11 Aug 2020 00:12:00

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:53', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c3f20b83-6287-4a42-8219-396353ebab4f'	System	11 Aug 2020 00:12:00
User entered 'None (1)'	System	11 Aug 2020 00:12:00



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:11:57', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c3f20b83-6287-4a42-8219-396353ebab4f'	System	11 Aug 2020 00:12:00
User entered '10 Aug 2020 19:11'	System	11 Aug 2020 00:12:00

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 4'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:57:57', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a5d79443-1f2c-43f1-a9b5-d84f09c861d1'	System	11 Aug 2020 23:58:17
User entered 'None (1)'	System	11 Aug 2020 23:58:17

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a5d79443-1f2c-43f1-a9b5-d84f09c861d1'	System	11 Aug 2020 23:58:17
User entered 'No (N)'	System	11 Aug 2020 23:58:17

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:06', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a5d79443-1f2c-43f1-a9b5-d84f09c861d1'	System	11 Aug 2020 23:58:17
User entered 'No (N)'	System	11 Aug 2020 23:58:17

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a5d79443-1f2c-43f1-a9b5-d84f09c861d1'	System	11 Aug 2020 23:58:17
User entered 'None (1)'	System	11 Aug 2020 23:58:17



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a5d79443-1f2c-43f1-a9b5-d84f09c861d1'	System	11 Aug 2020 23:58:17
User entered '11 Aug 2020 18:58'	System	11 Aug 2020 23:58:17

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 5'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:38', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'db3fa696-ea3e-4ce1-a15a-d3631bac94af'	System	13 Aug 2020 01:45:56
User entered 'None (1)'	System	13 Aug 2020 01:45:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:42', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'db3fa696-ea3e-4ce1-a15a-d3631bac94af'	System	13 Aug 2020 01:45:56
User entered 'No (N)'	System	13 Aug 2020 01:45:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'db3fa696-ea3e-4ce1-a15a-d3631bac94af'	System	13 Aug 2020 01:45:56
User entered 'No (N)'	System	13 Aug 2020 01:45:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'db3fa696-ea3e-4ce1-a15a-d3631bac94af'	System	13 Aug 2020 01:45:56
User entered 'None (1)'	System	13 Aug 2020 01:45:56



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:45:52', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'db3fa696-ea3e-4ce1-a15a-d3631bac94af'	System	13 Aug 2020 01:45:56
User entered '12 Aug 2020 20:45'	System	13 Aug 2020 01:45:56

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 6'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:19:55', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e46b2a63-07bb-4547-af06-2ee4058805d6'	System	14 Aug 2020 00:20:15
User entered 'None (1)'	System	14 Aug 2020 00:20:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:19:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e46b2a63-07bb-4547-af06-2ee4058805d6'	System	14 Aug 2020 00:20:15
User entered 'No (N)'	System	14 Aug 2020 00:20:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:02', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e46b2a63-07bb-4547-af06-2ee4058805d6'	System	14 Aug 2020 00:20:15
User entered 'No (N)'	System	14 Aug 2020 00:20:15

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:06', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e46b2a63-07bb-4547-af06-2ee4058805d6'	System	14 Aug 2020 00:20:15
User entered 'None (1)'	System	14 Aug 2020 00:20:15



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e46b2a63-07bb-4547-af06-2ee4058805d6'	System	14 Aug 2020 00:20:15
User entered '13 Aug 2020 19:20'	System	14 Aug 2020 00:20:15

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 7'	System	08 Aug 2020 15:37:23

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:36', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '31ea662b-a85b-4f26-8330-5604831529c0'	System	15 Aug 2020 03:38:56
User entered 'None (1)'	System	15 Aug 2020 03:38:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:41', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '31ea662b-a85b-4f26-8330-5604831529c0'	System	15 Aug 2020 03:38:56
User entered 'No (N)'	System	15 Aug 2020 03:38:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '31ea662b-a85b-4f26-8330-5604831529c0'	System	15 Aug 2020 03:38:56
User entered 'No (N)'	System	15 Aug 2020 03:38:56

US3062167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '31ea662b-a85b-4f26-8330-5604831529c0'	System	15 Aug 2020 03:38:56
User entered 'None (1)'	System	15 Aug 2020 03:38:56



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:38:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '31ea662b-a85b-4f26-8330-5604831529c0'	System	15 Aug 2020 03:38:56
User entered '14 Aug 2020 22:38'	System	15 Aug 2020 03:38:56

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:09:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:03', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:11', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:15', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'None (0)'	System	08 Aug 2020 16:10:39

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:28', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered 'No (N)'	System	08 Aug 2020 16:10:39

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T11:10:35', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bb6b3dff-9c77-482e-87a1-a1c97e82e69b'	System	08 Aug 2020 16:10:39
User entered '08 Aug 2020 11:10'	System	08 Aug 2020 16:10:39

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:37', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:43', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'None (0)'	System	09 Aug 2020 02:23:08

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:22:56', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered 'No (N)'	System	09 Aug 2020 02:23:08

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-08T21:23:05', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1a8bc155-db13-4527-b5af-074055636a26'	System	09 Aug 2020 02:23:08
User entered '08 Aug 2020 21:23'	System	09 Aug 2020 02:23:08

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 2'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:22', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:42', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'None (0)'	System	09 Aug 2020 23:30:03



US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:55', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered 'No (N)'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-09T18:29:58', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'af9d8073-753d-4faa-ab25-af0211cb1329'	System	09 Aug 2020 23:30:03
User entered '09 Aug 2020 18:29'	System	09 Aug 2020 23:30:03

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 3'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:16', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53



US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:31', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:36', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'None (0)'	System	11 Aug 2020 00:12:53

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered 'No (N)'	System	11 Aug 2020 00:12:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-10T19:12:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '793a04a9-83f8-4bc9-b3bd-c8bfe9ec14a7'	System	11 Aug 2020 00:12:53
User entered '10 Aug 2020 19:12'	System	11 Aug 2020 00:12:53

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 4'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:21', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:25', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:35', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'None (0)'	System	11 Aug 2020 23:58:51

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered 'No (N)'	System	11 Aug 2020 23:58:51

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-11T18:58:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'a791cf3a-6a0b-4709-b1b4-456463ffed09'	System	11 Aug 2020 23:58:51
User entered '11 Aug 2020 18:58'	System	11 Aug 2020 23:58:51



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 5'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:05', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:16', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'None (0)'	System	13 Aug 2020 01:46:34

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered 'No (N)'	System	13 Aug 2020 01:46:34

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-12T20:46:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'b77a953e-5f58-4027-97e3-62d766c2a33e'	System	13 Aug 2020 01:46:34
User entered '12 Aug 2020 20:46'	System	13 Aug 2020 01:46:34

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 6'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59



US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:30', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:36', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'None (0)'	System	14 Aug 2020 00:20:59

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered 'No (N)'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-13T19:20:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0835c049-f887-4c6d-a554-5a3e755ef338'	System	14 Aug 2020 00:20:59
User entered '13 Aug 2020 19:20'	System	14 Aug 2020 00:20:59

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 7'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:11', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:14', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'None (0)'	System	15 Aug 2020 03:39:45

US3062167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:39', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered 'No (N)'	System	15 Aug 2020 03:39:45



**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-08-14T22:39:42', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '8852ab6c-3acf-432e-af0e-a6e3df4f941e'	System	15 Aug 2020 03:39:45
User entered '14 Aug 2020 22:39'	System	15 Aug 2020 03:39:45

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 16:18:06
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '17 Aug 2020'	Janna Martinez (b) (4)	19 Aug 2020 16:18:06
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	19 Aug 2020 16:18:06
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Janna Martinez (b) (4)	19 Aug 2020 16:18:06
	(b) (4)	

US3062167

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 16:17:48
	(b) (4)	



**US3062167**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'I'	System	19 Aug 2020 16:17:48

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 16:12:58
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '24 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 16:12:58
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	26 Aug 2020 16:12:58
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 16:12:58

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 16:14:22
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:05:26
User entered 'I'	System	26 Aug 2020 16:14:22

**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	(b) (4) Brianna Burton (b) (4) (b) (4)	31 Aug 2020 18:28:58



**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered '31 Aug 2020'	Brianna Burton (b) (4)	31 Aug 2020 18:28:58

**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Contact Made (CONTACT MADE)'	Brianna Burton (b) (4)	31 Aug 2020 18:28:58

**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered empty.	(b) (4) Brianna Burton (b) (4)	31 Aug 2020 18:28:58

**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
User entered 'Yes (Y)'	(b) (4) Brianna Burton (b) (4) (b) (4)	31 Aug 2020 18:29:30

**US3062167**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:41
User entered 'I'	System	31 Aug 2020 18:29:30

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	08 Sep 2020 14:20:02
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Sherry Henning (b) (4)	08 Sep 2020 14:20:02
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[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 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	08 Sep 2020 14:20:02
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'VISIT2'	System	08 Sep 2020 14:20:02

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4) (b) (4)	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '07:36'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '8 Sep 2020 07:36'	System	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '97.7' F	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '58'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'bpm'	System	08 Sep 2020 17:44:46

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '15'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'breaths/min'	System	08 Sep 2020 17:44:46

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '130'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	08 Sep 2020 17:44:46

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '90'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	08 Sep 2020 17:44:46

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '09:45'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '8 Sep 2020 09:45'	System	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '98.4' F	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '56'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'bpm'	System	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '16'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'breaths/min'	System	08 Sep 2020 17:44:46

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '138'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '85'	Colton King (b) (4)	08 Sep 2020 17:44:46
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	08 Sep 2020 17:44:46

US3062167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:44:55
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 17:44:55
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	

US3062167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:20:31

US3062167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '09:08'	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '8 Sep 2020 09:08'	System	08 Sep 2020 14:20:31

US3062167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	08 Sep 2020 14:20:31
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'ONCE'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:20:31

US3062167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:45:14
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 17:45:14
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '07:52'	Colton King (b) (4)	08 Sep 2020 17:45:14
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '8 Sep 2020 07:52'	System	08 Sep 2020 17:45:14

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	08 Sep 2020 17:45:25
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colton King (b) (4) (b) (4)	08 Sep 2020 17:45:25

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:45:25
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '07:53'	Colton King (b) (4)	08 Sep 2020 17:45:25
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '8 Sep 2020 07:53'	System	08 Sep 2020 17:45:25

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colton King (b) (4) (b) (4)	08 Sep 2020 17:45:25

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	08 Sep 2020 17:45:25
	(b) (4)	



**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Colton King (b) (4)	08 Sep 2020 17:45:25
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered empty.	System	08 Sep 2020 17:45:25

US3062167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	08 Sep 2020 17:45:31
	(b) (4)	

**US3062167**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	08 Sep 2020 17:45:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:42:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4791ba58-3575-4d01-b077-23ff4a9fc166'	System	08 Sep 2020 14:43:12
User entered 'Yes (Y)'	System	08 Sep 2020 14:43:12

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:42:57', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4791ba58-3575-4d01-b077-23ff4a9fc166'	System	08 Sep 2020 14:43:12
User entered '98.4'	System	08 Sep 2020 14:43:12

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:04', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4791ba58-3575-4d01-b077-23ff4a9fc166'	System	08 Sep 2020 14:43:12
User entered 'No (N)'	System	08 Sep 2020 14:43:12



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:09', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4791ba58-3575-4d01-b077-23ff4a9fc166'	System	08 Sep 2020 14:43:12
User entered '08 Sep 2020 09:43'	System	08 Sep 2020 14:43:12

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 09:28'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 11:58'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40



US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 12:53'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 2'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f46644b7-d66a-49ae-ae4-02f421edb207'	System	10 Sep 2020 01:15:51
User entered 'Yes (Y)'	System	10 Sep 2020 01:15:51

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f46644b7-d66a-49ae-ace4-02f421edb207'	System	10 Sep 2020 01:15:51
User entered '95.7'	System	10 Sep 2020 01:15:51

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:36', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f46644b7-d66a-49ae-ae4-02f421edb207'	System	10 Sep 2020 01:15:51
User entered 'No (N)'	System	10 Sep 2020 01:15:51



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:39', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f46644b7-d66a-49ae-ae4-02f421edb207'	System	10 Sep 2020 01:15:51
User entered '09 Sep 2020 20:15'	System	10 Sep 2020 01:15:51

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 3'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:06:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6a96b0f5-37f4-4547-860e-de5f88d7a6e4'	System	11 Sep 2020 01:07:25
User entered 'Yes (Y)'	System	11 Sep 2020 01:07:25

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6a96b0f5-37f4-4547-860e-de5f88d7a6e4'	System	11 Sep 2020 01:07:25
User entered '96.4'	System	11 Sep 2020 01:07:25

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6a96b0f5-37f4-4547-860e-de5f88d7a6e4'	System	11 Sep 2020 01:07:25
User entered 'No (N)'	System	11 Sep 2020 01:07:25

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:22', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6a96b0f5-37f4-4547-860e-de5f88d7a6e4'	System	11 Sep 2020 01:07:25
User entered '10 Sep 2020 20:07'	System	11 Sep 2020 01:07:25



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 4'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:20:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1dcf535a-c4cf-4c9c-9caa-c5d0b19a46ac'	System	12 Sep 2020 00:21:28
User entered 'Yes (Y)'	System	12 Sep 2020 00:21:28

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:14', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1dcf535a-c4cf-4c9c-9caa-c5d0b19a46ac'	System	12 Sep 2020 00:21:28
User entered '96.8'	System	12 Sep 2020 00:21:28

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1dcf535a-c4cf-4c9c-9caa-c5d0b19a46ac'	System	12 Sep 2020 00:21:28
User entered 'No (N)'	System	12 Sep 2020 00:21:28

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1dcf535a-c4cf-4c9c-9caa-c5d0b19a46ac'	System	12 Sep 2020 00:21:28
User entered '11 Sep 2020 19:21'	System	12 Sep 2020 00:21:28

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 5'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:11:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd2964a8a-b322-470b-8644-3bce94bd5574'	System	12 Sep 2020 20:11:56
User entered 'Yes (Y)'	System	12 Sep 2020 20:11:56

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:11:47', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd2964a8a-b322-470b-8644-3bce94bd5574' User entered '96.9'	System	12 Sep 2020 20:11:56
	System	12 Sep 2020 20:11:56

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:11:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd2964a8a-b322-470b-8644-3bce94bd5574'	System	12 Sep 2020 20:11:56
User entered 'No (N)'	System	12 Sep 2020 20:11:56

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:11:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd2964a8a-b322-470b-8644-3bce94bd5574'	System	12 Sep 2020 20:11:56
User entered '12 Sep 2020 15:11'	System	12 Sep 2020 20:11:56

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:20:31



US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 6'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 7'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:46:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0c07b455-8cee-48e1-8a8c-47c5b6b7187a'	System	15 Sep 2020 05:48:11
User entered 'Yes (Y)'	System	15 Sep 2020 05:48:11

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0c07b455-8cee-48e1-8a8c-47c5b6b7187a'	System	15 Sep 2020 05:48:11
User entered '95.6'	System	15 Sep 2020 05:48:11

US3062167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:03', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0c07b455-8cee-48e1-8a8c-47c5b6b7187a'	System	15 Sep 2020 05:48:11
User entered 'No (N)'	System	15 Sep 2020 05:48:11

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:08', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '0c07b455-8cee-48e1-8a8c-47c5b6b7187a'	System	15 Sep 2020 05:48:11
User entered '15 Sep 2020 00:48'	System	15 Sep 2020 05:48:11

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c9d4b5e0-8b2c-4b70-be75-01750ceb745e'	System	08 Sep 2020 14:43:52
User entered 'None (1)'	System	08 Sep 2020 14:43:52

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:25', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c9d4b5e0-8b2c-4b70-be75-01750ceb745e'	System	08 Sep 2020 14:43:52
User entered 'No (N)'	System	08 Sep 2020 14:43:52

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c9d4b5e0-8b2c-4b70-be75-01750ceb745e'	System	08 Sep 2020 14:43:52
User entered 'No (N)'	System	08 Sep 2020 14:43:52

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:35', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c9d4b5e0-8b2c-4b70-be75-01750ceb745e'	System	08 Sep 2020 14:43:52
User entered 'None (1)'	System	08 Sep 2020 14:43:52

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c9d4b5e0-8b2c-4b70-be75-01750ceb745e'	System	08 Sep 2020 14:43:52
User entered '08 Sep 2020 09:43'	System	08 Sep 2020 14:43:52

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 09:28'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 11:58'	System	08 Sep 2020 14:20:31



US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 12:53'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 2'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '182eea87-eda4-43b8-b203-d65d44ab379c'	System	10 Sep 2020 01:39:41
User entered 'None (1)'	System	10 Sep 2020 01:39:41

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:50', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '182eea87-eda4-43b8-b203-d65d44ab379c'	System	10 Sep 2020 01:39:41
User entered 'No (N)'	System	10 Sep 2020 01:39:41

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '182eea87-eda4-43b8-b203-d65d44ab379c'	System	10 Sep 2020 01:39:41
User entered 'No (N)'	System	10 Sep 2020 01:39:41

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:15:58', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '182eea87-eda4-43b8-b203-d65d44ab379c'	System	10 Sep 2020 01:39:41
User entered 'None (1)'	System	10 Sep 2020 01:39:41

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '182eea87-eda4-43b8-b203-d65d44ab379c'	System	10 Sep 2020 01:39:41
User entered '09 Sep 2020 20:16'	System	10 Sep 2020 01:39:41



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 3'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:28', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2c483892-66d0-435f-969b-109d5228b05b'	System	11 Sep 2020 01:07:55
User entered 'None (1)'	System	11 Sep 2020 01:07:55

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:35', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2c483892-66d0-435f-969b-109d5228b05b'	System	11 Sep 2020 01:07:55
User entered 'No (N)'	System	11 Sep 2020 01:07:55

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:38', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2c483892-66d0-435f-969b-109d5228b05b'	System	11 Sep 2020 01:07:55
User entered 'No (N)'	System	11 Sep 2020 01:07:55

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2c483892-66d0-435f-969b-109d5228b05b'	System	11 Sep 2020 01:07:55
User entered 'None (1)'	System	11 Sep 2020 01:07:55

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:53', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2c483892-66d0-435f-969b-109d5228b05b'	System	11 Sep 2020 01:07:55
User entered '10 Sep 2020 20:07'	System	11 Sep 2020 01:07:55



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 4'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:30', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1ba92f38-4999-4506-9751-0da75fb053e4'	System	12 Sep 2020 00:22:04
User entered 'None (1)'	System	12 Sep 2020 00:22:04

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:38', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1ba92f38-4999-4506-9751-0da75fb053e4'	System	12 Sep 2020 00:22:04
User entered 'No (N)'	System	12 Sep 2020 00:22:04

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1ba92f38-4999-4506-9751-0da75fb053e4'	System	12 Sep 2020 00:22:04
User entered 'No (N)'	System	12 Sep 2020 00:22:04

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:21:55', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1ba92f38-4999-4506-9751-0da75fb053e4'	System	12 Sep 2020 00:22:04
User entered 'None (1)'	System	12 Sep 2020 00:22:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '1ba92f38-4999-4506-9751-0da75fb053e4'	System	12 Sep 2020 00:22:04
User entered '11 Sep 2020 19:22'	System	12 Sep 2020 00:22:04



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 5'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '91fd3f28-db3e-4212-b36e-e7d57d74f1fc'	System	12 Sep 2020 20:12:35
User entered 'None (1)'	System	12 Sep 2020 20:12:35

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '91fd3f28-db3e-4212-b36e-e7d57d74f1fc'	System	12 Sep 2020 20:12:35
User entered 'No (N)'	System	12 Sep 2020 20:12:35

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '91fd3f28-db3e-4212-b36e-e7d57d74f1fc'	System	12 Sep 2020 20:12:35
User entered 'No (N)'	System	12 Sep 2020 20:12:35

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '91fd3f28-db3e-4212-b36e-e7d57d74f1fc'	System	12 Sep 2020 20:12:35
User entered 'None (1)'	System	12 Sep 2020 20:12:35

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:30', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '91fd3f28-db3e-4212-b36e-e7d57d74f1fc'	System	12 Sep 2020 20:12:35
User entered '12 Sep 2020 15:12'	System	12 Sep 2020 20:12:35



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 6'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40



US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 7'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9bf4cdeb-a9df-4069-8627-9ac645d4548e'	System	15 Sep 2020 05:48:31
User entered 'None (1)'	System	15 Sep 2020 05:48:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:17', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9bf4cdeb-a9df-4069-8627-9ac645d4548e'	System	15 Sep 2020 05:48:31
User entered 'No (N)'	System	15 Sep 2020 05:48:31

US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:21', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9bf4cdeb-a9df-4069-8627-9ac645d4548e'	System	15 Sep 2020 05:48:31
User entered 'No (N)'	System	15 Sep 2020 05:48:31



US3062167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9bf4cdeb-a9df-4069-8627-9ac645d4548e'	System	15 Sep 2020 05:48:31
User entered 'None (1)'	System	15 Sep 2020 05:48:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9bf4cdeb-a9df-4069-8627-9ac645d4548e'	System	15 Sep 2020 05:48:31
User entered '15 Sep 2020 00:48'	System	15 Sep 2020 05:48:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:43:55', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:05', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27



US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:09', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:11', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:15', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'None (0)'	System	08 Sep 2020 14:44:27

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:21', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered 'No (N)'	System	08 Sep 2020 14:44:27

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-08T09:44:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'cfa3a97f-f1fd-4a5f-b5d0-6367de97a774'	System	08 Sep 2020 14:44:27
User entered '08 Sep 2020 09:44'	System	08 Sep 2020 14:44:27

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 09:28'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 11:58'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '08 Sep 2020 12:53'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 2'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:21', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:27', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'None (0)'	System	10 Sep 2020 01:39:23

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered 'No (N)'	System	10 Sep 2020 01:39:23

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-09T20:16:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd3cf2364-798b-4e6f-88d0-8cb36384313e'	System	10 Sep 2020 01:39:23
User entered '09 Sep 2020 20:16'	System	10 Sep 2020 01:39:23

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 3'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:07:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:08', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30



US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:11', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:14', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:17', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'None (0)'	System	11 Sep 2020 01:08:30

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered 'No (N)'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-10T20:08:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '73428868-f4e3-4339-b783-c2c46f987078'	System	11 Sep 2020 01:08:30
User entered '10 Sep 2020 20:08'	System	11 Sep 2020 01:08:30

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 4'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:14', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:26', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:30', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'None (0)'	System	12 Sep 2020 00:22:52

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered 'No (N)'	System	12 Sep 2020 00:22:52



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-11T19:22:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '07e0cef7-c18e-4e8f-83d8-62e0f3569801'	System	12 Sep 2020 00:22:52
User entered '11 Sep 2020 19:22'	System	12 Sep 2020 00:22:52

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 5'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:38', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:43', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'None (0)'	System	12 Sep 2020 20:13:04

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:12:58', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered 'No (N)'	System	12 Sep 2020 20:13:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-12T15:13:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c078ba5f-41da-4e0b-9d79-8958e3f76f1d'	System	12 Sep 2020 20:13:04
User entered '12 Sep 2020 15:13'	System	12 Sep 2020 20:13:04

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 6'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	05 Mar 2021 05:08:40

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:20:31



**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Sep 2020 14:20:31
User entered 'Day 7'	System	08 Sep 2020 14:20:31

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:37', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57

US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:42', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'None (0)'	System	15 Sep 2020 05:48:57



US3062167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:47', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered 'No (N)'	System	15 Sep 2020 05:48:57

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-09-15T00:48:52', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'aa8048b5-ce70-40f1-b43a-a0408fa930b9'	System	15 Sep 2020 05:48:57
User entered '15 Sep 2020 00:48'	System	15 Sep 2020 05:48:57

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:20:31

**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	16 Sep 2020 21:08:14
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '16 Sep 2020'	Colton King (b) (4)	16 Sep 2020 21:08:14
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	16 Sep 2020 21:08:14
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Colton King (b) (4)	16 Sep 2020 21:08:14
	(b) (4)	



**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	16 Sep 2020 21:08:01
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	16 Sep 2020 21:08:01

US3062167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:18:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 15:18:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	23 Sep 2020 15:18:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 15:18:38
User entered empty.	Janna Martinez (b) (4)	23 Sep 2020 15:18:38
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '22 Sep 2020'	Janna Martinez (b) (4)	23 Sep 2020 15:18:38
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	23 Sep 2020 15:18:38
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	23 Sep 2020 15:18:38
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	23 Sep 2020 15:18:44
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	23 Sep 2020 15:18:44



**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:36:24
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '29 Sep 2020'	Janna Martinez (b) (4)	10 Oct 2020 14:36:24
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	10 Oct 2020 14:36:24
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	10 Oct 2020 14:36:24
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:36:27
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	10 Oct 2020 14:36:27

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:36:46
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '10 Oct 2020'	Janna Martinez (b) (4)	10 Oct 2020 14:36:46
	(b) (4)	



**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[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 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	10 Oct 2020 14:36:46
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'VISIT3'	System	10 Oct 2020 14:36:46

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '10 Oct 2020'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '08:00'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '10 Oct 2020 08:00'	System	10 Oct 2020 14:37:15

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Temperature** (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '97.7' F	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	



**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '62'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'bpm'	System	10 Oct 2020 14:37:15

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'breaths/min'	System	10 Oct 2020 14:37:15

US3062167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '127'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	10 Oct 2020 14:37:15

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '73'	Janna Martinez (b) (4)	10 Oct 2020 14:37:15
	(b) (4)	



**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'mmHg'	System	10 Oct 2020 14:37:15

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	10 Oct 2020 14:37:20
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	10 Oct 2020 14:37:20
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:37:37
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '10 Oct 2020'	Janna Martinez (b) (4)	10 Oct 2020 14:37:37
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered '08:08'	Janna Martinez (b) (4)	10 Oct 2020 14:37:37
	(b) (4)	



**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered '10 Oct 2020 08:08'	System	10 Oct 2020 14:37:37

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:40:05
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	10 Oct 2020 14:37:51
	(b) (4)	

**US3062167**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	10 Oct 2020 14:37:51

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 64'	System	08 Aug 2020 15:37:23

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-10T08:19:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '3b51873d-18e7-4390-8d35-9bfd0971f016'	System	10 Oct 2020 13:20:24
User entered 'No (N)'	System	10 Oct 2020 13:20:24

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-10T08:19:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '3b51873d-18e7-4390-8d35-9bfd0971f016'	System	10 Oct 2020 13:20:24
User entered 'No (N)'	System	10 Oct 2020 13:20:24

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-10T08:19:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '3b51873d-18e7-4390-8d35-9bfd0971f016'	System	10 Oct 2020 13:20:24
User entered '10 Oct 2020 08:19:40'	System	10 Oct 2020 13:20:24

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 15:37:23



**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 71'	System	08 Aug 2020 15:37:23

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-17T08:17:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4928d292-2319-4626-b020-b2a2b8e5905c'	System	17 Oct 2020 13:17:51
User entered 'No (N)'	System	17 Oct 2020 13:17:51

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-17T08:17:28', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4928d292-2319-4626-b020-b2a2b8e5905c'	System	17 Oct 2020 13:17:51
User entered 'No (N)'	System	17 Oct 2020 13:17:51

**US3062167**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-17T08:17:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '4928d292-2319-4626-b020-b2a2b8e5905c'	System	17 Oct 2020 13:17:51
User entered '17 Oct 2020 08:17:48'	System	17 Oct 2020 13:17:51

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 78'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-23T21:16:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '411a7b76-af46-4c55-a139-7b55d4335704'	System	24 Oct 2020 02:17:37
User entered 'Yes (Y)'	System	24 Oct 2020 02:17:37

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-23T21:16:46', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '411a7b76-af46-4c55-a139-7b55d4335704'	System	24 Oct 2020 02:17:37
User entered 'No (N)'	System	24 Oct 2020 02:17:37

US3062167

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-23T21:17:01', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '411a7b76-af46-4c55-a139-7b55d4335704'	System	24 Oct 2020 02:17:37
User entered 'No (N)'	System	24 Oct 2020 02:17:37

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-23T21:17:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '411a7b76-af46-4c55-a139-7b55d4335704'	System	24 Oct 2020 02:17:37
User entered 'No (N)'	System	24 Oct 2020 02:17:37

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-10-23T21:17:32', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '411a7b76-af46-4c55-a139-7b55d4335704'	System	24 Oct 2020 02:17:37
User entered '23 Oct 2020 21:17:32'	System	24 Oct 2020 02:17:37

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 92'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-07T12:59:40', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'dc39adc8-7def-4517-bba5-d3b1e15e92bd'	System	07 Nov 2020 19:00:26
User entered 'Yes (Y)'	System	07 Nov 2020 19:00:26

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-07T12:59:47', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'dc39adc8-7def-4517-bba5-d3b1e15e92bd'	System	07 Nov 2020 19:00:26
User entered 'No (N)'	System	07 Nov 2020 19:00:26

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-07T12:59:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'dc39adc8-7def-4517-bba5-d3b1e15e92bd'	System	07 Nov 2020 19:00:26
User entered 'No (N)'	System	07 Nov 2020 19:00:26

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-07T13:00:19', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'dc39adc8-7def-4517-bba5-d3b1e15e92bd'	System	07 Nov 2020 19:00:26
User entered 'No (N)'	System	07 Nov 2020 19:00:26

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-07T13:00:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'dc39adc8-7def-4517-bba5-d3b1e15e92bd'	System	07 Nov 2020 19:00:26
User entered '07 Nov 2020 13:00:23'	System	07 Nov 2020 19:00:26

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 99'	System	08 Aug 2020 15:37:23



**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-12T06:13:39', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '029cb58f-fe97-42fe-b061-112d360b815c'	System	12 Nov 2020 12:13:55
User entered 'No (N)'	System	12 Nov 2020 12:13:55

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-12T06:13:49', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '029cb58f-fe97-42fe-b061-112d360b815c'	System	12 Nov 2020 12:13:55
User entered 'No (N)'	System	12 Nov 2020 12:13:55

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-12T06:13:53', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '029cb58f-fe97-42fe-b061-112d360b815c'	System	12 Nov 2020 12:13:55
User entered '12 Nov 2020 06:13:53'	System	12 Nov 2020 12:13:55

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered 'Day 106'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-19T00:01:34', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f853dbf7-2a6a-4a4e-9930-e4c6248acc78'	System	19 Nov 2020 06:01:52
User entered 'No (N)'	System	19 Nov 2020 06:01:52

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-19T00:01:45', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f853dbf7-2a6a-4a4e-9930-e4c6248acc78'	System	19 Nov 2020 06:01:52
User entered 'No (N)'	System	19 Nov 2020 06:01:52



**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-19T00:01:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'f853dbf7-2a6a-4a4e-9930-e4c6248acc78' User entered '19 Nov 2020 00:01:48'	System	19 Nov 2020 06:01:52
	System	19 Nov 2020 06:01:52

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:08:40
Data entry locked.	System	08 Aug 2020 15:37:23
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 15:37:23

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-11-23T10:54:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '457f994f-d203-4b23-bbf4-90ca040c8667'	System	23 Nov 2020 16:54:30
User entered 'No (N)'	System	23 Nov 2020 16:54:30

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-11-23T10:54:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '457f994f-d203-4b23-bbf4-90ca040c8667'	System	23 Nov 2020 16:54:30
User entered 'No (N)'	System	23 Nov 2020 16:54:30

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-23T10:54:28', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '457f994f-d203-4b23-bbf4-90ca040c8667'	System	23 Nov 2020 16:54:30
User entered '23 Nov 2020 10:54:28'	System	23 Nov 2020 16:54:30

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-11-30T08:34:42', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'eb2a66d3-8861-46d8-9615-e62c0c15554b'	System	30 Nov 2020 14:34:59
User entered 'No (N)'	System	30 Nov 2020 14:34:59

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-11-30T08:34:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'eb2a66d3-8861-46d8-9615-e62c0c15554b'	System	30 Nov 2020 14:34:59
User entered 'No (N)'	System	30 Nov 2020 14:34:59

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-11-30T08:34:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'eb2a66d3-8861-46d8-9615-e62c0c15554b'	System	30 Nov 2020 14:34:59
User entered '30 Nov 2020 08:34:54'	System	30 Nov 2020 14:34:59

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-07T09:01:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bcb07905-620c-482a-b792-d17cac5a2c20'	System	07 Dec 2020 15:01:55
User entered 'No (N)'	System	07 Dec 2020 15:01:55

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-12-07T09:01:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bcb07905-620c-482a-b792-d17cac5a2c20'	System	07 Dec 2020 15:01:55
User entered 'No (N)'	System	07 Dec 2020 15:01:55

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-07T09:01:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'bcb07905-620c-482a-b792-d17cac5a2c20' User entered '07 Dec 2020 09:01:54'	System	07 Dec 2020 15:01:55
	System	07 Dec 2020 15:01:55

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-14T11:34:51', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'Yes (Y)'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-12-14T11:35:02', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'Yes (Y)'	System	14 Dec 2020 17:36:22



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please 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 (8fb216f651141ce2)', Time: '2020-12-14T11:35:06', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-14T11:35:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'Yes (Y)'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '0'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:35:48', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '1'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please 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 (8fb216f651141ce2)', Time: '2020-12-14T11:35:54', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-14T11:36:08', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered 'No (N)'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-14T11:36:12', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2b614588-6756-4d81-a8a9-71996fc2a4e6'	System	14 Dec 2020 17:36:22
User entered '14 Dec 2020 11:36:12'	System	14 Dec 2020 17:36:22

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-21T07:19:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72736c56-932d-4bcd-a854-d95fea7e6c61'	System	21 Dec 2020 13:19:26
User entered 'No (N)'	System	21 Dec 2020 13:19:26

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-12-21T07:19:16', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72736c56-932d-4bcd-a854-d95fea7e6c61'	System	21 Dec 2020 13:19:26
User entered 'No (N)'	System	21 Dec 2020 13:19:26

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-21T07:19:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72736c56-932d-4bcd-a854-d95fea7e6c61'	System	21 Dec 2020 13:19:26
User entered '21 Dec 2020 07:19:23'	System	21 Dec 2020 13:19:26

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2020-12-28T07:22:03', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ab65ab11-1514-4aba-a411-d5a918f0722c'	System	28 Dec 2020 13:22:19
User entered 'No (N)'	System	28 Dec 2020 13:22:19



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2020-12-28T07:22:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ab65ab11-1514-4aba-a411-d5a918f0722c'	System	28 Dec 2020 13:22:19
User entered 'No (N)'	System	28 Dec 2020 13:22:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2020-12-28T07:22:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ab65ab11-1514-4aba-a411-d5a918f0722c'	System	28 Dec 2020 13:22:19
User entered '28 Dec 2020 07:22:13'	System	28 Dec 2020 13:22:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-01-04T00:12:16', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '27d4eaf0-05f5-4f75-8187-e1e61c16d0d6'	System	04 Jan 2021 06:12:27
User entered 'No (N)'	System	04 Jan 2021 06:12:27

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-01-04T00:12:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '27d4eaf0-05f5-4f75-8187-e1e61c16d0d6'	System	04 Jan 2021 06:12:27
User entered 'No (N)'	System	04 Jan 2021 06:12:27

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-01-04T00:12:23', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '27d4eaf0-05f5-4f75-8187-e1e61c16d0d6'	System	04 Jan 2021 06:12:27
User entered '04 Jan 2021 00:12:23'	System	04 Jan 2021 06:12:27



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-01-11T09:36:25', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9e768037-b7f4-46b8-a63f-f806ac31974d'	System	11 Jan 2021 15:36:39
User entered 'No (N)'	System	11 Jan 2021 15:36:39

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-01-11T09:36:29', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9e768037-b7f4-46b8-a63f-f806ac31974d'	System	11 Jan 2021 15:36:39
User entered 'No (N)'	System	11 Jan 2021 15:36:39

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-01-11T09:36:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '9e768037-b7f4-46b8-a63f-f806ac31974d' User entered '11 Jan 2021 09:36:33'	System	11 Jan 2021 15:36:39
	System	11 Jan 2021 15:36:39

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-01-27T00:03:06', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6d13411e-b6fb-4460-b5ff-fc3250d5b32f'	System	27 Jan 2021 06:03:20
User entered 'No (N)'	System	27 Jan 2021 06:03:20

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-01-27T00:03:11', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6d13411e-b6fb-4460-b5ff-fc3250d5b32f'	System	27 Jan 2021 06:03:20
User entered 'No (N)'	System	27 Jan 2021 06:03:20

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-01-27T00:03:16', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6d13411e-b6fb-4460-b5ff-fc3250d5b32f'	System	27 Jan 2021 06:03:20
User entered '27 Jan 2021 00:03:16'	System	27 Jan 2021 06:03:20

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-02-01T06:57:59', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72a8cce0-c39e-42ab-9cfd-15f094ea9b08'	System	01 Feb 2021 12:58:19
User entered 'No (N)'	System	01 Feb 2021 12:58:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-02-01T06:58:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72a8cce0-c39e-42ab-9cfd-15f094ea9b08'	System	01 Feb 2021 12:58:19
User entered 'No (N)'	System	01 Feb 2021 12:58:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-01T06:58:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '72a8cce0-c39e-42ab-9cfd-15f094ea9b08'	System	01 Feb 2021 12:58:19
User entered '01 Feb 2021 06:58:13'	System	01 Feb 2021 12:58:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-02-12T07:01:20', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7c8fc31d-a817-4f6a-9459-dfec37c8a98e'	System	12 Feb 2021 13:01:38
User entered 'No (N)'	System	12 Feb 2021 13:01:38

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-02-12T07:01:24', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7c8fc31d-a817-4f6a-9459-dfec37c8a98e'	System	12 Feb 2021 13:01:38
User entered 'No (N)'	System	12 Feb 2021 13:01:38

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-12T07:01:33', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '7c8fc31d-a817-4f6a-9459-dfec37c8a98e'	System	12 Feb 2021 13:01:38
User entered '12 Feb 2021 07:01:33'	System	12 Feb 2021 13:01:38

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-02-15T05:48:07', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'be9a4757-586c-4cde-8172-407e8fc779ed'	System	15 Feb 2021 11:48:21
User entered 'No (N)'	System	15 Feb 2021 11:48:21

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-02-15T05:48:15', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'be9a4757-586c-4cde-8172-407e8fc779ed'	System	15 Feb 2021 11:48:21
User entered 'No (N)'	System	15 Feb 2021 11:48:21



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-15T05:48:18', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'be9a4757-586c-4cde-8172-407e8fc779ed'	System	15 Feb 2021 11:48:21
User entered '15 Feb 2021 05:48:18'	System	15 Feb 2021 11:48:21

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-02-22T06:10:58', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ef74a28e-5a75-4dc3-921e-0fb9b863e695'	System	22 Feb 2021 12:11:16
User entered 'No (N)'	System	22 Feb 2021 12:11:16

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-02-22T06:11:10', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ef74a28e-5a75-4dc3-921e-0fb9b863e695'	System	22 Feb 2021 12:11:16
User entered 'No (N)'	System	22 Feb 2021 12:11:16

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-22T06:11:13', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'ef74a28e-5a75-4dc3-921e-0fb9b863e695'	System	22 Feb 2021 12:11:16
User entered '22 Feb 2021 06:11:13'	System	22 Feb 2021 12:11:16

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-03-01T09:01:41-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '5247ee91-1a53-4c47-bd18-b517db2a9ed2'	System	01 Mar 2021 15:01:53
User entered 'No (N)'	System	01 Mar 2021 15:01:53

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-03-01T09:01:46-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '5247ee91-1a53-4c47-bd18-b517db2a9ed2'	System	01 Mar 2021 15:01:53
User entered 'No (N)'	System	01 Mar 2021 15:01:53

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-03-01T09:01:48-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '5247ee91-1a53-4c47-bd18-b517db2a9ed2' User entered '01 Mar 2021 09:01:48'	System	01 Mar 2021 15:01:53
	System	01 Mar 2021 15:01:53

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-03-11T06:27:00-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c5ebab05-3600-4adc-a6e1-10312fb86734'	System	11 Mar 2021 12:27:10
User entered 'No (N)'	System	11 Mar 2021 12:27:10

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-03-11T06:27:04-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c5ebab05-3600-4adc-a6e1-10312fb86734'	System	11 Mar 2021 12:27:10
User entered 'No (N)'	System	11 Mar 2021 12:27:10

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-03-11T06:27:07-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c5ebab05-3600-4adc-a6e1-10312fb86734'	System	11 Mar 2021 12:27:10
User entered '11 Mar 2021 06:27:07'	System	11 Mar 2021 12:27:10

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-03-17T14:56:40-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '035a746a-edef-4d03-9ae9-6b4197159320' User entered 'No (N)'	System	17 Mar 2021 19:56:52
	System	17 Mar 2021 19:56:52

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-03-17T14:56:45-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '035a746a-edef-4d03-9ae9-6b4197159320'	System	17 Mar 2021 19:56:52
User entered 'No (N)'	System	17 Mar 2021 19:56:52



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-03-17T14:56:48-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '035a746a-edef-4d03-9ae9-6b4197159320' User entered '17 Mar 2021 14:56:48'	System	17 Mar 2021 19:56:52
	System	17 Mar 2021 19:56:52

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-03-22T08:37:06-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6c87a313-de93-4df6-9233-e96dad0d6aff'	System	22 Mar 2021 13:37:19
User entered 'No (N)'	System	22 Mar 2021 13:37:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-03-22T08:37:11-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6c87a313-de93-4df6-9233-e96dad0d6aff'	System	22 Mar 2021 13:37:19
User entered 'No (N)'	System	22 Mar 2021 13:37:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-03-22T08:37:14-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '6c87a313-de93-4df6-9233-e96dad0d6aff'	System	22 Mar 2021 13:37:19
User entered '22 Mar 2021 08:37:14'	System	22 Mar 2021 13:37:19

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-03-29T07:01:05-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '12ca2ea0-4f94-4330-9006-8a5fc00dcab4'	System	29 Mar 2021 12:01:17
User entered 'No (N)'	System	29 Mar 2021 12:01:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-03-29T07:01:09-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '12ca2ea0-4f94-4330-9006-8a5fc00dcab4'	System	29 Mar 2021 12:01:17
User entered 'No (N)'	System	29 Mar 2021 12:01:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-03-29T07:01:12-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '12ca2ea0-4f94-4330-9006-8a5fc00dcab4' User entered '29 Mar 2021 07:01:12'	System	29 Mar 2021 12:01:17
	System	29 Mar 2021 12:01:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-04-05T06:48:01-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '28982e19-c4b5-4cd4-903e-7c045ef5357b' User entered 'No (N)'	System	05 Apr 2021 11:48:12
	System	05 Apr 2021 11:48:12

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-04-05T06:48:06-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '28982e19-c4b5-4cd4-903e-7c045ef5357b' User entered 'No (N)'	System	05 Apr 2021 11:48:12
	System	05 Apr 2021 11:48:12

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-04-05T06:48:09-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '28982e19-c4b5-4cd4-903e-7c045ef5357b' User entered '05 Apr 2021 06:48:09'	System	05 Apr 2021 11:48:12
	System	05 Apr 2021 11:48:12

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-04-12T00:01:49-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2bfece80-12b2-4f11-b65c-62cd59937bbf'	System	12 Apr 2021 05:01:58
User entered 'No (N)'	System	12 Apr 2021 05:01:58

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-04-12T00:01:52-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2bfece80-12b2-4f11-b65c-62cd59937bbf'	System	12 Apr 2021 05:01:58
User entered 'No (N)'	System	12 Apr 2021 05:01:58



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-04-12T00:01:54-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2bfece80-12b2-4f11-b65c-62cd59937bbf'	System	12 Apr 2021 05:01:58
User entered '12 Apr 2021 00:01:54'	System	12 Apr 2021 05:01:58

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-04-19T00:01:52-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c7cebc97-cab7-4282-b968-64b11c225c15'	System	19 Apr 2021 05:02:01
User entered 'No (N)'	System	19 Apr 2021 05:02:01

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-04-19T00:01:56-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c7cebc97-cab7-4282-b968-64b11c225c15'	System	19 Apr 2021 05:02:01
User entered 'No (N)'	System	19 Apr 2021 05:02:01

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-04-19T00:01:59-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'c7cebc97-cab7-4282-b968-64b11c225c15'	System	19 Apr 2021 05:02:01
User entered '19 Apr 2021 00:01:59'	System	19 Apr 2021 05:02:01

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-04-26T06:27:30-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2a63ca89-413f-4f9d-8b49-26cc147c79a8'	System	26 Apr 2021 12:06:35
User entered 'No (N)'	System	26 Apr 2021 12:06:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-04-26T06:27:47-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2a63ca89-413f-4f9d-8b49-26cc147c79a8'	System	26 Apr 2021 12:06:35
User entered 'No (N)'	System	26 Apr 2021 12:06:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-04-26T06:27:51-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: '2a63ca89-413f-4f9d-8b49-26cc147c79a8'	System	26 Apr 2021 12:06:35
User entered '26 Apr 2021 06:27:51'	System	26 Apr 2021 12:06:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (8fb216f651141ce2)', Time: '2021-05-03T07:00:04-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd89b54a7-5e82-4d0f-8edb-43ed79dc9cfa'	System	03 May 2021 12:00:17
User entered 'No (N)'	System	03 May 2021 12:00:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (8fb216f651141ce2)', Time: '2021-05-03T07:00:11-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd89b54a7-5e82-4d0f-8edb-43ed79dc9cfa'	System	03 May 2021 12:00:17
User entered 'No (N)'	System	03 May 2021 12:00:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-05-03T07:00:14-05:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'd89b54a7-5e82-4d0f-8edb-43ed79dc9cfa'	System	03 May 2021 12:00:17
User entered '03 May 2021 07:00:14'	System	03 May 2021 12:00:17

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:28:35



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:28:35



**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:28:35
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:28:35

**US3062167**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:59:37**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:07:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-28T15:04:59-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e748f185-20f3-4985-8474-333987f19ac8'	System	28 Feb 2021 21:05:07
User entered 'No (N)'	System	28 Feb 2021 21:05:07

**US3062167**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:07:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8fb216f651141ce2)', Time: '2021-02-28T15:05:03-06:00', User OID: 'PatientReportedOutcome (US3062167)', ODM File OID: 'e748f185-20f3-4985-8474-333987f19ac8' User entered '28 Feb 2021 15:05:03'	System	28 Feb 2021 21:05:07
	System	28 Feb 2021 21:05:07



**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User entered 'Yes (Y)'	Jeri King (b) (4)	02 Nov 2020 23:12:53

**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User entered '02 Nov 2020'	Jeri King (b) (4)	02 Nov 2020 23:12:53

**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jeri King (b) (4)	02 Nov 2020 23:12:53

**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User entered empty.	Jeri King (b) (4)	02 Nov 2020 23:12:53

**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User entered 'Yes (Y)'	Jeri King (b) (4)	02 Nov 2020 23:13:00

**US3062167**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:14:32
User entered 'I'	System	02 Nov 2020 23:13:00

**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	10 Dec 2020 16:37:57
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '10 Dec 2020'	(b) (4) Riley King (b) (4) (b) (4)	10 Dec 2020 16:37:57



**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	10 Dec 2020 16:37:57
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Riley King (b) (4)	10 Dec 2020 16:37:57
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	10 Dec 2020 16:38:02
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'I'	System	10 Dec 2020 16:38:02

**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 22:49:20
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '4 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	05 Jan 2021 22:49:20

**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	05 Jan 2021 22:49:20
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Riley King (b) (4)	05 Jan 2021 22:49:20
	(b) (4)	



**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 22:49:24
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'I'	System	05 Jan 2021 22:49:24

**US3062167**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	05 Feb 2021 14:43:25
	(b) (4)	

US3062167

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 21:42:15
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Colton King (b) (4)	08 Feb 2021 19:55:17
	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Feb 2021 14:43:25
User entered '1 Feb 2021'	Sherry Henning (b) (4)	05 Feb 2021 14:43:25
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	05 Feb 2021 14:43:25
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	05 Feb 2021 14:43:25
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	05 Feb 2021 14:51:35
	(b) (4)	

**US3062167**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'I'	System	05 Feb 2021 14:51:35



US3062167

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:02:38
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.	Janna Martinez (b) (4)	31 Mar 2021 19:46:12
' answered with 'data corrected' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:05:58
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 17:50:45
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 17:50:45
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	01 Mar 2021 17:50:45
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'VISIT4'	System	01 Mar 2021 17:50:45

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Feb 2021'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '14:58'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered '26 Feb 2021 14:58'	System	31 Mar 2021 19:47:02



US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '98.2' F	Janna Martinez (b) (4)	31 Mar 2021 19:47:02
	(b) (4)	

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02
	(b) (4)	

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '66'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'bpm'	System	31 Mar 2021 19:47:02

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '16'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'breaths/min'	System	31 Mar 2021 19:47:02

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '135'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02
	(b) (4)	



**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'mmHg'	System	31 Mar 2021 19:47:02

US3062167

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '76'	Janna Martinez (b) (4)	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'mmHg'	System	31 Mar 2021 19:47:02

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47

US3062167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:53
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
	(b) (4)	
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:49:00
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	20 Apr 2021 16:09:56
Signature has been broken.	(b) (4)	
	marissa Mueller (b) (4)	20 Apr 2021 16:09:41
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	20 Apr 2021 16:09:41
	(b) (4)	
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:54:42
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:54:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	

US3062167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Audit	User	Time (GMT)
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' answered with 'Visit 4- only symptom directed is required OL Day 29- investigator is required to assess lymph nodes and injection arm ie part of a physical.  If visit 4 did not require lab but OI D29 did, we would document as such as each tab is visit/protocol derived. ' (Site from DM).	marissa Mueller (b) (4) (b) (4)	02 Apr 2021 13:34:46
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed Physical examination/immunogenicity if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:39:44
User closed query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:39:44
Query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' answered with 'per protocol, px not required at this visit. This would be the same if immunogenicity was drawn at one and not the other per protocol. Correct as entered' (Site from DM).	marissa Mueller (b) (4) (b) (4)	31 Mar 2021 15:18:07
User opened query 'Per CDM (RQ): Please note as the Visit 4 Day209 and OL-D29 is done on the same day but Physical examination in Visit 4 is NO, as per CCGs the physical examination to be done in Visit 4 kindly update for consistency of data across both Visits. Thanks' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:01:08

US3062167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:01:08
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'data correct as entered as Physical is not required for visit 4 but is required for OL-D29' (Site from DM).	Janna Martinez (b) (4)	30 Mar 2021 19:08:26
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however Physical examination performed on Visit 4 Day 209 is No and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:06:16
User entered 'No (N)'	Sherry Henning (b) (4)	01 Mar 2021 17:52:24



US3062167

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:14:53
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
Signature has been broken.	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 16:09:41
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	20 Apr 2021 16:09:41
User signature succeeded.	(b) (4) Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	(b) (4) Sherry Henning (b) (4)	01 Mar 2021 17:52:24

US3062167

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 17:52:43
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 17:52:43

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '15:05'	Sherry Henning (b) (4)	01 Mar 2021 17:52:43
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered '26 Feb 2021 15:05'	System	01 Mar 2021 17:52:43

US3062167

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 17:52:49
	(b) (4)	

**US3062167**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:48:47
User entered 'I'	System	01 Mar 2021 17:52:49

**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User entered 'Yes (Y)'	Colton King (b) (4)	06 Apr 2021 17:47:48



**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User entered '5 Apr 2021'	Colton King (b) (4)	06 Apr 2021 17:47:48

**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	06 Apr 2021 17:47:48

**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User entered empty.	(b) (4) Colton King (b) (4)	06 Apr 2021 17:47:48

**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	06 Apr 2021 17:48:51

**US3062167**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:43:49
User entered 'I'	System	06 Apr 2021 17:48:51

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:18:38
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:12:42
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:37

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:18:38
User entered '09:25'	Colton King (b) (4)	14 Dec 2020 15:12:42
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '10 Dec 2020 09:25'	System	14 Dec 2020 15:12:42



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:37

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:18:38
User entered 'Safety Call (Safety Call)'	Colton King (b) (4)	14 Dec 2020 15:12:42
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:18:38
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:12:42
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 1 (Day 1)'	Colton King (b) (4)	14 Dec 2020 15:15:14

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '8 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered missing code ND - Not Done; reason for change Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:35:44
	(b) (4)	
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	21 Dec 2020 15:35:44
User entered empty.	System	14 Dec 2020 15:15:14

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered missing code ND - Not Done; reason for change Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:35:44
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:15:14



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:02
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:00
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:09
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:10
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:18
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:31
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:39
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:41
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:28
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:14
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 2 (Day 2)'	Colton King (b) (4)	14 Dec 2020 15:15:58

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '9 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered missing code ND - Not Done; reason for	marissa Mueller (b) (4)	21 Dec 2020 15:35:44
change Data Entry Error	(b) (4)	
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	21 Dec 2020 15:35:44
User entered empty.	System	14 Dec 2020 15:15:58

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered missing code ND - Not Done; reason for change Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:35:44
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:15:58

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:01
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:19:57
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:05
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:11
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:17
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:27
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:37
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:35
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:25
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:15:58
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 3 (Day 3)'	Colton King (b) (4)	14 Dec 2020 15:17:09

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:31
User entered '99'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	14 Dec 2020 15:17:09

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:08
User entered '96.5' F	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:45
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:37
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:43
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:55
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:53
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:03
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:21
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:18
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:07
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:17:09
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 4 (Day 4)'	Colton King (b) (4)	14 Dec 2020 15:46:27

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '11 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	14 Dec 2020 16:13:51
User entered '12 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	



**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	14 Dec 2020 15:46:27

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.0' F	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:40
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:22:55
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:02
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:00
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:07
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 15:46:27
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Day 5 (Day 5)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '12 Dec 2020'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	14 Dec 2020 16:10:24

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.9' F	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:28
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:33
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:36
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:40
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:23:45
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:10:24
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 6 (Day 6)'	Colton King (b) (4)	14 Dec 2020 16:11:13

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '13 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	14 Dec 2020 16:17:11
User entered '14 Dec 2020'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	14 Dec 2020 16:11:13

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.0' F	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:07
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:12
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:14
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:16
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:11:13
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Day 7 (Day 7)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '14 Dec 2020'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	14 Dec 2020 16:19:08

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:40
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:43
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:46
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:49
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:49:40
User closed query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:49:32
Query 'please verify source of 12/15 indicates this symptom started on 12/14' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 19:59:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 19:59:03
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:31
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).		04 Feb 2021 20:28:01
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:49:56
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:49:44
Query 'please verify source of 12/15 indicates this symptom started on 12/14' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 19:59:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 19:59:03
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:29
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).		04 Feb 2021 20:27:54
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:49:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:49:50
Query 'please verify source of 12/15 indicates this symptom started on 12/14' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 19:59:19
User entered 'Mild (Mild)' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 19:59:03
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:28
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify source of 12/15 indicates this symptom started on 12/14' (Site from CRA).		04 Feb 2021 20:27:47
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:24:53
User entered 'Mild (Mild)'	Colton King (b) (4)	14 Dec 2020 16:19:08
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 8 (Day 8)'	(b) (4) Riley King (b) (4) (b) (4)	17 Dec 2020 14:10:40

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '15 Dec 2020'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '96'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	



**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	17 Dec 2020 14:10:40

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:48:57
User closed query 'please verify as 97.8 per source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:48:46
Query 'please verify as 97.8 per source' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 20:00:04
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	08 Feb 2021 19:59:53
	(b) (4), (b) (6)	04 Feb 2021 20:34:46
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify as 97.8 per source' (Site from CRA).		04 Feb 2021 20:26:53
User entered '97.6' F	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:03
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:25:13
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:06
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:09
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	



US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:11
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:20
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:24
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:25
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:26:31
User entered 'Mild (Mild)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	17 Dec 2020 14:10:40
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 9 (Day 9)'	(b) (4) Riley King (b) (4) (b) (4)	18 Dec 2020 19:42:12

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '16 Dec 2020'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	18 Dec 2020 19:42:12

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:28:28
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:28:32
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:28:34
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:28:47
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:28:45
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:12
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Day 10 (Day 10)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '17 Dec 2020'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	18 Dec 2020 19:42:49

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.0' F	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:11
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:16
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:18
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:23
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:25
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:42:49
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 11 (Day 11)'	(b) (4) Riley King (b) (4) (b) (4)	18 Dec 2020 19:43:35

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '18 Dec 2020'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	18 Dec 2020 19:43:35

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:48
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:53
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:55
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:59
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:30:01
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:43:35
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 12 (Day 12)'	(b) (4) Riley King (b) (4) (b) (4)	18 Dec 2020 19:44:29

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '19 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:36:18
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	21 Dec 2020 15:36:12
User entered '18 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:36:12
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	18 Dec 2020 19:44:29
User entered '19 Dec 2020'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	



**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	18 Dec 2020 19:44:29

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:30:59
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:31:03
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:31:05
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'please verify as mild as per source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:50:45
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:50:41
Query 'please verify as mild as per source' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 20:00:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	08 Feb 2021 20:00:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:35:07
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify as mild as per source' (Site from CRA).		04 Feb 2021 20:31:54
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:31:09
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:50:51
User closed query 'please verify as none as per source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:50:48
Query 'please verify as none as per source' answered with 'updated' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 20:00:48
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 20:00:33
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:35:10
DataPoint Verified.		04 Feb 2021 20:34:10
User opened query 'please verify as none as per source' (Site from CRA).		04 Feb 2021 20:32:17
User entered 'Mild (Mild)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	



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Form: Symptom Log (12)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	18 Dec 2020 19:44:29
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 13 (Day 13)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:41:25

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '20 Dec 2020'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	27 Dec 2020 20:41:25

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.0' F	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	



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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:32:41
User entered 'Mild (Mild)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (13)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:32:45
User entered 'Mild (Mild)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Form: Symptom Log (13)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Form: Symptom Log (13)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	



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Form: Symptom Log (13)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Form: Symptom Log (13)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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Form: Symptom Log (13)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:41:25
	(b) (4)	



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 14 (Day 14)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:42:11

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '21 Dec 2020'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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**Form: Symptom Log (14)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	27 Dec 2020 20:42:11

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:33:05
User entered 'Mild (Mild)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	



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Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:33:09
User entered 'Mild (Mild)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:11
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 15 (Day 15)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:42:44

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '22 Dec 2020'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	27 Dec 2020 20:42:44

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.1' F	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:33:41
User entered 'Mild (Mild)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (15)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:42:44
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 16 (Day 16)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:43:19

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '23 Dec 2020'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Form: Symptom Log (16)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '99'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	



**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	27 Dec 2020 20:43:19

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '97.8' F	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:19
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Day 17 (Day 17)'	(b) (4) Riley King (b) (4) (b) (4)	27 Dec 2020 20:43:54

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '24 Dec 2020'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '0'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered '%'	System	27 Dec 2020 20:43:54

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered '98.0' F	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:34:10
User entered 'None (None)'	Riley King (b) (4)	27 Dec 2020 20:43:54
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:33:21
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:33:21

US3062167

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
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).	(b) (4), (b) (6)	21 Dec 2020 08:54:46
User closed query 'Per CDM: Response "awaiting test results" is noted. Please update if results are available. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:54:41
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	18 Dec 2020 15:05:13
Query 'Per CDM: Response "awaiting test results" is noted. Please update if results are available. Thank you.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	18 Dec 2020 15:05:03
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	18 Dec 2020 15:04:55
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	18 Dec 2020 15:04:55
User opened query 'Per CDM: Response "awaiting test results" is noted. Please update if results are available. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 18:11:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 18:11:08
Query 'Data is required. Please complete.' answered with 'awaiting test results' (Site from System).	Colton King (b) (4)	14 Dec 2020 15:34:10
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 15:33:21
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:33:21

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:33:21
	(b) (4)	

**US3062167**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Colton King (b) (4)	14 Dec 2020 15:33:21

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Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:33:21
	(b) (4)	

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered 'No (N)'	Colton King (b) (4)	14 Dec 2020 15:33:21

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:33:21
	(b) (4)	



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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:16:59
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:33:21
	(b) (4)	

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**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User entered 'I'	System	18 Dec 2020 15:04:55

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

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Generated On: 09 Jun 2021 14:59:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
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User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	



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Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:06:39

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:59:37

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:25
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:06:39
	(b) (4)	

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Folder: Covid-19 Assessment 10 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:59:37

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:20:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:17:40
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:05:44

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 3 (Day 3)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered 'Yes (Y)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered '11 Dec 2020'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 5 (Day 5)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:59:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered 'Yes (Y)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered '14 Dec 2020'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 7 (Day 7)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:59:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:16:26
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:38:05
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:37:08
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:59:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:16:28
User entered '16 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Dec 2020 18:04:11
	(b) (4)	
User entered '26 Nov 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:37

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 30DEC2020 recorded for COVID PCR Saliva Day 21, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 16:37:51
Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 30DEC2020 recorded for COVID PCR Saliva Day 21, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate.' answered with 'updated' (Site from DM).	Colton King (b) (4) (b) (4)	12 Jan 2021 19:30:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 30DEC2020 recorded for COVID PCR Saliva Day 21, however, this sample is missing in EDC. Please clarify if this sample was collected, and if so, please update the database by recording this data, as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 15:33:09
User accepted default value 'Day 9 (Day 9)'	marissa Mueller (b) (4) (b) (4)	21 Dec 2020 15:37:08



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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:16:11
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:38:05
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:37:08
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:59:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:16:13
User entered '18 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Dec 2020 18:04:11
	(b) (4)	
User entered '28 Nov 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 14 (Day 14)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:59:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 19:30:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 19:30:25
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:30:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 18:04:11
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	22 Dec 2020 18:04:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:38:05
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:37:08
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 21 (Day 21)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:59:37

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:04
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 19:30:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 19:30:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:30:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 18:04:11
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	22 Dec 2020 18:04:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:38:05
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:37:08
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:05
User entered '30 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:30:25
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User accepted default value 'Day 28 (Day 28)'	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:59:37

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	04 Feb 2021 14:54:06
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 19:30:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 19:30:25
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:30:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 18:04:11
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	22 Dec 2020 18:04:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 15:38:05
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Dec 2020 15:38:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 15:37:08
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

**US3062167**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:17:42
User entered '13 Jan 2021' reason for change: Data Entry Error	marissa Mueller (b) (4)	04 Feb 2021 14:54:06
	(b) (4)	
User entered empty.	marissa Mueller (b) (4)	21 Dec 2020 15:37:08
	(b) (4)	

US3062167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:06
User closed query 'Per ETRTR, Please complete saliva collection page. thanks!' (Site from CRA).	(b) (4), (b) (6)	01 Feb 2021 22:17:54
Query 'Per ETRTR, Please complete saliva collection page. thanks!' answered with 'updated' (Site from CRA).	Colton King (b) (4)	12 Jan 2021 19:31:01
	(b) (4)	
User opened query 'Per ETRTR, Please complete saliva collection page. thanks!' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 21:24:53
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:35:14
	(b) (4)	

US3062167

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:47:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	21 Dec 2020 15:43:35
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:00:35
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:35:14

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:06
User entered 'Clinic (Clinic)'	Colton King (b) (4)	14 Dec 2020 15:35:14
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered 'SICKD1'	System	14 Dec 2020 15:35:14

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	



**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '14:15'	Colton King (b) (4)	14 Dec 2020 15:36:49

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered '10 Dec 2020 14:15'	System	14 Dec 2020 15:36:49

US3062167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '178.0' cm	Colton King (b) (4)	14 Dec 2020 15:36:49
DataPoint set to visible.	(b) (4) System	14 Dec 2020 15:35:14

US3062167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '107.4' kg	Colton King (b) (4)	14 Dec 2020 15:36:49
DataPoint set to visible.	System	14 Dec 2020 15:35:14

US3062167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 18:12:15
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	marissa Mueller (b) (4)	15 Dec 2020 18:14:47
	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Dec 2020 15:36:49
User entered '96.5' F	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered 'Oral (Oral)'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered empty.	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	



**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '52'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered 'bpm'	System	14 Dec 2020 15:36:49

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '14'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered 'breaths/min'	System	14 Dec 2020 15:36:49

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '138'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered 'mmHg'	System	14 Dec 2020 15:36:49

US3062167

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:05:35
User entered '64'	Colton King (b) (4)	14 Dec 2020 15:36:49
	(b) (4)	

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User entered 'mmHg'	System	14 Dec 2020 15:36:49



**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:07:30
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:42:14
	(b) (4)	

US3062167

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:07:30
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:42:14
	(b) (4)	

US3062167

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:37

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:08:32
User entered 'Yes (Y)'	Colton King (b) (4)	14 Dec 2020 15:42:46

**US3062167**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:24:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:08:32
User entered '10 Dec 2020'	Colton King (b) (4)	14 Dec 2020 15:42:46
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:29
User entered 'Yes (Y)'	Sherry Henning (b) (4)	22 Jan 2021 18:12:45
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:29
User entered '13 Jan 2021'	Sherry Henning (b) (4)	22 Jan 2021 18:12:45
	(b) (4)	



US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:29
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	22 Jan 2021 18:12:45
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered 'SICKD28'	System	22 Jan 2021 18:12:45

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered 'Yes (Y)'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '13 Jan 2021'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '16:05'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered '13 Jan 2021 16:05'	System	28 Jan 2021 17:38:24

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '178.0' cm	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
DataPoint set to visible.	System	22 Jan 2021 18:12:45

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '107.4' kg	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
DataPoint set to visible.	System	22 Jan 2021 18:12:45



US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '97.0' F	marissa Mueller (b) (4)	28 Jan 2021 17:38:24

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered 'Oral (Oral)'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered empty.	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '75'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered 'bpm'	System	28 Jan 2021 17:38:24

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '12'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered 'breaths/min'	System	28 Jan 2021 17:38:24

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User entered '124'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24



**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered 'mmHg'	System	28 Jan 2021 17:38:24

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:09:48
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 08:36:53
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	marissa Mueller (b) (4)	28 Jan 2021 17:38:27
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	28 Jan 2021 17:38:24
User entered '58'	marissa Mueller (b) (4)	28 Jan 2021 17:38:24
	(b) (4)	

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User entered 'mmHg'	System	28 Jan 2021 17:38:24

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27

**US3062167**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:10:08
User entered 'Yes (Y)'	marissa Mueller (b) (4)	28 Jan 2021 17:38:41
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:10:08
User entered '13 Jan 2021'	marissa Mueller (b) (4)	28 Jan 2021 17:38:41
	(b) (4)	

US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:37

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:11:48
User entered 'Yes (Y)'	marissa Mueller (b) (4)	28 Jan 2021 17:38:49



US3062167

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:59:37

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:36:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:11:48
User entered '13 Jan 2021'	marissa Mueller (b) (4)	28 Jan 2021 17:38:49
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:03:45

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:03:45
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[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 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Clinic (Clinic)'	Colton King (b) (4)	28 Jan 2021 20:03:45

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:03:45

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:04:06
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[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 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:27:25

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:04:06



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:27:25

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:04:06

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:59:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Placebo (Placebo)'	Colton King (b) (4)	28 Jan 2021 20:04:06
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Placebo (Placebo)'	Colton King (b) (4)	28 Jan 2021 20:04:06

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Placebo (Placebo)'	Colton King (b) (4)	28 Jan 2021 20:04:06

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:04:06
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '1'	System	28 Jan 2021 20:04:06

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'I'	System	28 Jan 2021 20:04:06



US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '180.3' cm	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '112.8' kg	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:59:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '34.69905'	System	28 Jan 2021 20:18:35
DataPoint set to visible.	System	28 Jan 2021 20:04:06

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '180.3' cm	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '112.8' kg	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:59:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '34.69905'	System	28 Jan 2021 20:18:35
DataPoint set to visible.	System	28 Jan 2021 20:04:06

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User accepted default value 'Pre-Dose (PREDOSE)'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '08:19'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Jan 2021 08:19'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 07:39:16
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Janna Martinez (b) (4)	28 Jan 2021 22:15:20
answered with 'PI DEEMED NOT CLINICALLY SIGNIFICANT' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Jan 2021 20:18:35
User entered '96.5' F	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '62'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'bpm'	System	28 Jan 2021 20:18:35



US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '16'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'breaths/min'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '128'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '74'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:59:37**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '180.3' cm	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:59:37**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '112.8' kg	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:59:37**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '34.69905'	System	28 Jan 2021 20:18:35
DataPoint set to visible.	System	28 Jan 2021 20:04:06

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User accepted default value 'Post-Dose (POSTDOSE)'	Colton King (b) (4) (b) (4)	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '10:31'	(b) (4) Colton King (b) (4) (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Jan 2021 10:31'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '97.6' F	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Oral (Oral)'	Colton King (b) (4)	28 Jan 2021 20:18:35



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '60'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'bpm'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '16'	Colton King (b) (4)	28 Jan 2021 20:18:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'breaths/min'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '117'	Colton King (b) (4)	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	28 Jan 2021 20:18:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '70'	Colton King (b) (4)	28 Jan 2021 20:18:35



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	28 Jan 2021 20:18:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:18:45

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:18:45

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:19:09

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Colton King (b) (4)	28 Jan 2021 20:19:09

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

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)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	(b) (4) Colton King (b) (4) (b) (4)	28 Jan 2021 20:19:09

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mRNA-1273'	System	28 Jan 2021 20:19:09
DataPoint set to visible.	System	28 Jan 2021 20:04:06

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:19:09



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '09:59'	Colton King (b) (4)	28 Jan 2021 20:19:09

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Jan 2021 09:59'	System	28 Jan 2021 20:19:09

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Left Arm (LEFT ARM)'	Colton King (b) (4)	28 Jan 2021 20:19:09

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'ONCE'	System	28 Jan 2021 20:19:09

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 20:19:09

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:19:25
	(b) (4)	

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:19:25

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '08:25'	Colton King (b) (4)	28 Jan 2021 20:19:25



**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Jan 2021 08:25'	System	28 Jan 2021 20:19:25

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:19:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'please verify +COVID test per lab portal and update AE tab' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 18:00:54
Query 'please verify +COVID test per lab portal and update AE tab' answered with 'Subject is still testing +COVID from initial COVID 19+ test on10DEC2020.' (Site from CRA).	Sherry Henning (b) (4)	02 Mar 2021 20:42:24
	(b) (4)	
User opened query 'please verify +COVID test per lab portal and update AE tab' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 18:14:13
User entered '26 Jan 2021'	Colton King (b) (4)	28 Jan 2021 20:19:35
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '08:27'	Colton King (b) (4)	28 Jan 2021 20:19:35

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Jan 2021 08:27'	System	28 Jan 2021 20:19:35

US3062167

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	28 Jan 2021 20:19:38
	(b) (4)	

**US3062167**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'I'	System	28 Jan 2021 20:19:38

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	08 Feb 2021 19:56:23



US3062167

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 04:12:15
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Correct as entered' (Site from System).	Colton King (b) (4)	22 Feb 2021 20:09:48
	(b) (4)	
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 00:41:21
User entered '8 Feb 2021'	Colton King (b) (4)	08 Feb 2021 19:56:23
	(b) (4)	

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	08 Feb 2021 19:56:23

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	(b) (4) Colton King (b) (4)	08 Feb 2021 19:56:23

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Colton King (b) (4)	08 Feb 2021 19:56:27

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'I'	System	08 Feb 2021 19:56:27

**US3062167**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '1'	System	08 Feb 2021 19:56:27
DataPoint set to visible.	System	08 Feb 2021 19:56:27

**US3062167**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 17:55:02
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 17:55:02
	(b) (4)	



**US3062167**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[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 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	01 Mar 2021 17:55:02
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'OLD29'	System	01 Mar 2021 17:55:02

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	01 Mar 2021 17:58:51

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '14:58'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Feb 2021 14:58'	System	01 Mar 2021 17:58:51

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '98.2' F	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	



**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '66'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'bpm'	System	01 Mar 2021 17:58:51

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'breaths/min'	System	01 Mar 2021 17:58:51

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '135'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	01 Mar 2021 17:58:51



**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '76'	Sherry Henning (b) (4)	01 Mar 2021 17:58:51
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	01 Mar 2021 17:58:51

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	01 Mar 2021 18:01:23

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '16:37'	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Feb 2021 16:37'	System	01 Mar 2021 18:01:23

US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:49
User entered '98.7' F reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:23
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:55
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:49
User entered '61' reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:23
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'bpm'	System	01 Mar 2021 18:01:49
User entered empty.	System	01 Mar 2021 18:01:23

US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:49
User entered '16' reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:23
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'breaths/min'	System	01 Mar 2021 18:01:49
User entered empty.	System	01 Mar 2021 18:01:23

US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:49
User entered '126' reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:23
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	01 Mar 2021 18:01:49
User entered empty.	System	01 Mar 2021 18:01:23



US3062167

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Mar 2021 18:01:49
User entered '78' reason for change: Data Entry Error	Sherry Henning (b) (4)	01 Mar 2021 18:01:49
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Mar 2021 18:01:23
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:01:23
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mmHg'	System	01 Mar 2021 18:01:49
User entered empty.	System	01 Mar 2021 18:01:23

**US3062167**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 18:05:25
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 18:05:25

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 18:07:49
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:07:49
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

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)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Sherry Henning (b) (4)	01 Mar 2021 18:07:49

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'mRNA-1273'	System	01 Mar 2021 18:07:49
DataPoint set to visible.	System	08 Feb 2021 19:56:27



**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '26 Feb 2021'	Sherry Henning (b) (4)	01 Mar 2021 18:07:49
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered '16:05'	Sherry Henning (b) (4)	01 Mar 2021 18:07:49
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered '26 Feb 2021 16:05'	System	01 Mar 2021 18:07:49

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	01 Mar 2021 18:07:49
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'ONCE'	System	01 Mar 2021 18:07:49

**US3062167**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 18:07:49

**US3062167**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	01 Mar 2021 18:08:19
	(b) (4)	

**US3062167**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'I'	System	01 Mar 2021 18:08:19



**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Janna Martinez (b) (4)	11 Mar 2021 17:22:40

**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered '08 Mar 2021'	Janna Martinez (b) (4)	11 Mar 2021 17:22:40

**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	11 Mar 2021 17:22:40

**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered empty.	Janna Martinez (b) (4)	11 Mar 2021 17:22:40

**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User entered 'Yes (Y)'	Janna Martinez (b) (4)	11 Mar 2021 17:22:45

**US3062167**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:16:25
User entered 'I'	System	11 Mar 2021 17:22:45

**US3062167**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 14:40:10
	(b) (4)	

US3062167

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '2 Apr 2021'	Colton King (b) (4)	05 Apr 2021 14:40:10
	(b) (4)	



**US3062167**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Colton King (b) (4)	05 Apr 2021 14:40:10
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 14:40:10

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '2 Apr 2021'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '16:03'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 16:03'	System	05 Apr 2021 14:41:01

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '98.4' F	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'Oral (Oral)'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	



**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered empty.	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '60'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 14:41:01

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '16'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 14:41:01

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '131'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 14:41:01

US3062167

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '76'	Colton King (b) (4)	05 Apr 2021 14:41:01
	(b) (4)	



**US3062167**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 14:41:01

**US3062167**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	05 Apr 2021 14:41:13
	(b) (4)	

US3062167

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4) (b) (4)	09 Apr 2021 13:21:38
User entered empty.	Colton King (b) (4) (b) (4)	05 Apr 2021 14:41:13

**US3062167**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	05 Apr 2021 14:42:07
	(b) (4)	

US3062167

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '2 Apr 2021'	Colton King (b) (4)	05 Apr 2021 14:42:07
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
	(b) (4)	
User entered '16:06'	Colton King (b) (4)	05 Apr 2021 14:42:07
	(b) (4)	

**US3062167**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 16:06'	System	05 Apr 2021 14:42:07

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:59:37**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:43
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:38:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	02 Nov 2020 22:40:02
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 14:31:28
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:41:19
User entered	System	03 Nov 2020 18:41:06
'USA-US090-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 18:41:06

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:39:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:39:51
	(b) (4)	
Data point term sent to Coder	System	02 Nov 2020 22:42:24
User entered 'Prostate Cancer'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Yes (Y)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'No (N)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'No (N)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '16 Oct 2020'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 22:42:19



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
DataPoint Un-verified.	Riley King (b) (4)	14 Jan 2021 20:48:04
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	14 Jan 2021 20:48:04
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Yes (Y)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 13:53:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' answered with 'Subject had prostatectomy on 1/8/21.' (Site from Safety).	Riley King (b) (4)	14 Jan 2021 20:54:37
	(b) (4)	
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	14 Jan 2021 20:52:07
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	14 Jan 2021 20:52:07
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	14 Jan 2021 20:48:04
DataPoint Un-verified.	Riley King (b) (4)	14 Jan 2021 20:48:04
	(b) (4)	
User entered '8 Jan 2021' reason for change: New Information	Riley King (b) (4)	14 Jan 2021 20:48:04
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:37:27
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:41:10

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4)	13 Nov 2020 14:51:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:50:51
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Grade 4 (Grade 4)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Yes (Y)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19



US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'I'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'PV Query: Please update the causality of study drug to the event and study procedure to the event. Causality should be reported as "Related" or "Not related".' (Site from Safety). Query 'PV Query: Please update the causality of study drug to the event and study procedure to the event. Causality should be reported as "Related" or "Not related".' answered with 'updated per source' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:19:04
DataPoint Un-verified.	marissa Mueller (b) (4)	21 Nov 2020 01:19:31
	(b) (4)	
	marissa Mueller (b) (4)	21 Nov 2020 01:19:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Nov 2020 01:19:15
	(b) (4)	
User opened query 'PV Query: Please update the causality of study drug to the event and study procedure to the event. Causality should be reported as "Related" or "Not related".' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:52:00
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:06:36
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated per source' (Site from DM).	marissa Mueller (b) (4)	21 Nov 2020 01:19:36
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	21 Nov 2020 01:19:15
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	marissa Mueller (b) (4)	21 Nov 2020 01:19:15
	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:49:59
DataPoint Verified.		08 Nov 2020 14:39:07
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered 'Not Applicable (NOT APPLICABLE)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered '0'	Jeri King (b) (4)	02 Nov 2020 22:42:19

US3062167

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
User closed query 'Per DM CLR: RQ: Response noted, the check box is still ticked. The procedure recorded in Con Proc eCRF is a diagnostic procedure. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:03:52
Query 'Per DM CLR: RQ: Response noted, the check box is still ticked. The procedure recorded in Con Proc eCRF is a diagnostic procedure. Review and update as appropriate. Otherwise, clarify.' answered with 'Subject had prostatectomy on 1/8/21' (Site from DM).	Riley King (b) (4)	21 Jan 2021 16:47:07
	(b) (4)	
User opened query 'Per DM CLR: RQ: Response noted, the check box is still ticked. The procedure recorded in Con Proc eCRF is a diagnostic procedure. Review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 05:06:06
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:13:15
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'Item deleted' (Site from DM).	Jeri King (b) (4)	25 Nov 2020 23:40:01
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedure is a Diagnostic procedure rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:28:03
DataPoint Verified.		08 Nov 2020 14:39:07

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Jeri King (b) (4) [REDACTED]	02 Nov 2020 22:42:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		22 Jan 2021 16:50:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject had prostatectomy on 1/8/21. Subject recovered at this time. ' (Site from Safety).	Riley King (b) (4)	21 Jan 2021 16:47:56
DataPoint Un-verified.	(b) (4)	14 Jan 2021 20:52:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Riley King (b) (4)	14 Jan 2021 20:52:07
New Information	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:51:07
DataPoint Verified.		08 Nov 2020 14:39:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:39:07
User entered empty.	Jeri King (b) (4)	02 Nov 2020 22:42:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:11:40
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD PSA LEVEL ON 8/10/2020. However, this is not recorded in the ConProc eCRF (i.e., Blook work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:38:01
User closed query 'Per DM CLR: SAE Narrative = HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. 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)	09 Mar 2021 20:37:58
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PROSTATE BIOPSY ON 10/15/202. However, date of biopsy is 16OCT2020 in the ConProc eCRF. Please review and reconcile data as appropriate.' (Site from DM).		09 Mar 2021 20:37:40
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results as case narrative currently states the subject had a COVID illness visit and received treatment medications for COVID 19.' (Site from Safety).		02 Mar 2021 20:20:18
User closed query 'PV Query: Please send pathology report 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).		02 Mar 2021 20:20:15
Query 'PV Query: Please send pathology report 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 'Faxed' (Site from Safety).	Riley King (b) (4)	02 Mar 2021 15:17:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	02 Mar 2021 15:00:32
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD PSA LEVEL ON 8/10/2020. However, this is not recorded in the ConProc eCRF (i.e., Blook work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	02 Mar 2021 14:58:53
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PROSTATE BIOPSY ON 10/15/202. However, date of biopsy is 16OCT2020 in the ConProc eCRF. Please review and reconcile data as appropriate.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	02 Mar 2021 14:57:12
DataPoint Un-verified.	Riley King (b) (4)	02 Mar 2021 14:56:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED THAT HE HAD A PROSTATE BIOPSY. THE RESULTS OF THE BIOPSY WERE GIVEN TO THE SUBJECT THIS WEEK. SUBJECT HAS PROSTATE CANCER. HE REPORTS THAT HE IS SCHEDULED FOR PROSTATECTOMY ON 12/14/2020. RELEASE OF RECORDS MAILED TO SUBJECT FOR SIGNATURE. UPDATE 11/25/2020 - SUBJECT HAD PSA LEVEL ON 8/10/2020. PSA WAS 1.6 NG/ML WITH A REFERENCE RANGE OF 0.0-4.0. SUBJECT WAS REFERRED TO UROLOGIST FOR PROSTATE NODULE. SUBJECT REPORTS NO FAMILY HISTORY OF PROSTATE CANCER. SUBJECT HAD A PROSTATE BIOPSY ON 10/16/2020 WITH PATHOLOGY THAT CONFIRMED A DIAGNOSIS OF PROSTATE CANCER. HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. SUBJECT WILL BE HAVING A ROBOTIC ASSISTED LAPRASCOPIC RADICAL PROSTATECTOMY IN DECEMBER 2020. SUBJECT HAD FOLLOW UP VISIT AT STUDY SITE FOLLOWING A COVID ILLNESS VISIT. AT FOLLOW UP VISIT SUBJECT NOTIFIED STAFF OF PROSTATECTOMY THAT TOOK PLACE ON 1/8/2021. STAFF TOOK DOWN RELEVANT INFORMATION. SUBJECT HAD PREVIOUSLY SIGNED RELEASE OF RECORDS FORM. RELEASE OF RECORDS FAXED.' reason for change: New Information	Riley King (b) (4) (b) (4)	02 Mar 2021 14:56:56
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results as case narrative currently states the subject had a COVID illness visit and received treatment medications for COVID 19.' answered with 'Subject tested positive for COVID-19 at site, not during hospital stay. ' (Site from Safety).	Riley King (b) (4) (b) (4)	02 Mar 2021 14:55:51
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	04 Feb 2021 20:38:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. 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)	23 Jan 2021 06:38:32
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD A PROSTATE BIOPSY ON 10/15/202. However, date of biopsy is 16OCT2020 in the ConProc eCRF. Please review and reconcile data as appropriate.' (Site from DM).		23 Jan 2021 06:38:25
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD PSA LEVEL ON 8/10/2020. However, this is not recorded in the ConProc eCRF (i.e., Blook work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		23 Jan 2021 06:38:19
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available. ' canceled (Site from Safety).		22 Jan 2021 20:03:03
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results as case narrative currently states the subject had a COVID illness visit and received treatment medications for COVID 19.' (Site from Safety).		19 Jan 2021 19:32:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED THAT HE HAD A PROSTATE BIOPSY. THE RESULTS OF THE BIOPSY WERE GIVEN TO THE SUBJECT THIS WEEK. SUBJECT HAS PROSTATE CANCER. HE REPORTS THAT HE IS SCHEDULED FOR PROSTATECTOMY ON 12/14/2020. RELEASE OF RECORDS MAILED TO SUBJECT FOR SIGNATURE. UPDATE 11/25/2020 - SUBJECT HAD PSA LEVEL ON 8/10/2020. PSA WAS 1.6 NG/ML WITH A REFERENCE RANGE OF 0.0-4.0. SUBJECT WAS REFERRED TO UROLOGIST FOR PROSTATE NODULE. SUBJECT REPORTS NO FAMILY HISTORY OF PROSTATE CANCER. SUBJECT HAD A PROSTATE BIOPSY ON 10/15/2020 WITH PATHOLOGY THAT CONFIRMED A DIAGNOSIS OF PROSTATE CANCER. HE ALSO HAD TRANSRECTAL ULTRASOUND OF THE PROSTATE ON 10/16/2020. SUBJECT WILL BE HAVING A ROBOTIC ASSISTED LAPRASCOPIC RADICAL PROSTATECTOMY IN DECEMBER 2020. Subject had follow up visit at study site following a COVID illness visit. At follow up visit subject notified staff of prostatectomy that took place on 1/8/2021. Staff took down relevant information. Subject had previously signed release of records form. Release of records faxed.' reason for change: New Information	Riley King (b) (4) (b) (4)	14 Jan 2021 20:52:07
User opened query 'PV Query: Please send pathology report 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)	04 Dec 2020 22:02:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 20:36:40

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy. Please leave query open until information is available. ' answered with 'Lab provided' (Site from Safety). DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:40:25
	Jeri King (b) (4)	25 Nov 2020 23:37:38
User entered 'SUBJECT REPORTED THAT HE HAD A PROSTATE BIOPSY. THE RESULTS OF THE BIOPSY WERE GIVEN TO THE SUBJECT THIS WEEK. SUBJECT HAS PROSTATE CANCER. HE REPORTS THAT HE IS SCHEDULED FOR PROSTATECTOMY ON 12/14/2020. RELEASE OF RECORDS MAILED TO SUBJECT FOR SIGNATURE. Update 11/25/2020 - Subject had PSA level on 8/10/2020. PSA was 1.6 ng/ml with a reference range of 0.0-4.0. Subject was referred to Urologist for Prostate Nodule. Subject reports no family history of prostate cancer. Subject had a prostate biopsy on 10/15/2020 with pathology that confirmed a diagnosis of prostate cancer. He also had transrectal ultrasound of the prostate on 10/16/2020. Subject will be having a robotic assisted laprascopic radical prostatectomy in December 2020.' reason for change: Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:37:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:19:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy.' (Site from Safety).		23 Nov 2020 20:19:56



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:19:37
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		23 Nov 2020 20:19:37
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4) (b) (4)	21 Nov 2020 01:13:44
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy.' answered with 'pending records' (Site from Safety).	marissa Mueller (b) (4) (b) (4)	21 Nov 2020 01:13:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including details of the prostate biopsy). Please include units and reference ranges if applicable. Please provide the date of the biopsy.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:51:33

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:51:18
		08 Nov 2020 14:39:07
User entered 'Subject reported that he had a prostate biopsy. The results of the biopsy were given to the subject this week. Subject has prostate cancer. He reports that he is scheduled for Prostatectomy on 12/14/2020. Release of records mailed to subject for signature.'	Jeri King (b) (4)	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 22:42:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Nov 2020 22:42:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
Reviewed for Safety.		21 Dec 2020 15:51:48
User entered		21 Dec 2020 15:51:39
'USA-US090-2020-mRNA-1273-P301000014'		
User entered 'New'		21 Dec 2020 15:51:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
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)	18 Dec 2020 15:11:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 15:11:21
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 15:10:03
User entered 'COVID 19'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

US3062167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '08 Dec 2020'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:09:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Jan 2021 19:35:58
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:35:58
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Jan 2021 19:35:33
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:59:07
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Dec 2020). The event end date is reported as 22 Dec 2020; however, symptom of mild cough was still reported on that day.' (Site from Safety).		06 Mar 2021 20:06:40
Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Dec 2020). The event end date is reported as 22 Dec 2020; however, symptom of mild cough was still reported on that day.'	Colton King (b) (4)	08 Feb 2021 20:15:08
answered with 'updated' (Site from Safety).	(b) (4)	
User entered '23 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 20:15:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 20:38:49
DataPoint Verified.		04 Feb 2021 20:38:45
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Dec 2020). The event end date is reported as 22 Dec 2020; however, symptom of mild cough was still reported on that day.' (Site from Safety).		26 Jan 2021 12:08:50
User closed query 'PV Query: Event end date listed as 22 Dec 2020, which is when subject was still having symptoms. Please update end date to when symptoms have resolved.' (Site from Safety).		25 Jan 2021 19:51:23
Query 'PV Query: Event end date listed as 22 Dec 2020, which is when subject was still having symptoms. Please update end date to when symptoms have resolved.' answered with 'Correct as entered' (Site from Safety).	marissa Mueller (b) (4)	22 Jan 2021 20:12:55
	(b) (4)	
User opened query 'PV Query: Event end date listed as 22 Dec 2020, which is when subject was still having symptoms. Please update end date to when symptoms have resolved.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 14:08:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 21:31:38
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Colton King (b) (4)	12 Jan 2021 19:36:06
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)	12 Jan 2021 19:35:58
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	12 Jan 2021 19:35:58
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	12 Jan 2021 19:35:33
User entered '22 Dec 2020' reason for change: Data Entry Error	Colton King (b) (4)	12 Jan 2021 19:35:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	30 Dec 2020 16:26:44
User entered empty.	(b) (4), (b) (6)	
	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:09:27

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'I'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 21:31:44
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Colton King (b) (4)	12 Jan 2021 19:36:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	12 Jan 2021 19:35:58
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:27:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:09:27
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 15:09:27

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 15:09:27



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 20:01:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Dec 2020 20:01:30
	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 20:00:48
User entered 'Erectile Dysfunction'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '20 Nov 2020'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 20:00:16

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Dec 2020 20:00:16

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

US3062167

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 20:01:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 20:01:02
User entered 'No (N)' reason for change: Data Entry Error	Colton King (b) (4)	30 Dec 2020 20:01:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 20:00:16
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Related (NOT RELATED)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Related (NOT RELATED)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 20:00:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 20:00:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Colton King (b) (4)	30 Dec 2020 20:00:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 20:00:16
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'I'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Colton King (b) (4)	30 Dec 2020 20:00:16
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Dec 2020 20:01:02

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Dec 2020 20:00:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 18:29:00
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	(b) (4)	24 Feb 2021 18:29:00
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:27:59
Data point term sent to Coder	System	08 Feb 2021 20:12:49
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Colton King (b) (4)	08 Feb 2021 20:12:31
DataPoint Un-verified.	Colton King (b) (4)	08 Feb 2021 20:12:24
Coding entries removed.	(b) (4)	
	Colton King (b) (4)	08 Feb 2021 20:12:24
User entered 'POST OPERATIVE PAIN Generalized' reason for change: Data Entry Error	(b) (4)	08 Feb 2021 20:12:24
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location of POST OPERATIVE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).		23 Jan 2021 06:38:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 20:31:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 20:31:09
Data point term sent to Coder	System	14 Jan 2021 20:30:25
User entered 'Post operative pain'	Riley King (b) (4)	14 Jan 2021 20:30:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '9 Jan 2021'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Jan 2021 20:31:23
User entered empty; reason for change Per Query Resolution	Riley King (b) (4)	14 Jan 2021 20:31:23
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Jan 2021 20:30:19
User entered '08:00'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 20:31:23
User entered '9 Jan 2021 08:00'	System	14 Jan 2021 20:30:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Yes (Y)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 20:30:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	



**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

US3062167

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:31:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 20:31:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4)	14 Jan 2021 20:31:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:30:19
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:31:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 20:31:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4)	14 Jan 2021 20:31:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:30:19
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:31:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 20:31:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Riley King (b) (4)	14 Jan 2021 20:31:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 20:30:19
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'I'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

US3062167

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:56
User closed query 'Per CDM, DM CLR re-query: Response noted; however there is no procedure recorded to address this AE. Please update this field or record a therapeutic procedure which is within the AE timeframe. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 16:08:18
Query 'Per CDM, DM CLR re-query: Response noted; however there is no procedure recorded to address this AE. Please update this field or record a therapeutic procedure which is within the AE timeframe. Review and update as appropriate. ' answered with 'Reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	12 Feb 2021 17:38:25
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	12 Feb 2021 17:38:15
User entered '0' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	12 Feb 2021 17:38:15
User closed query ' Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:52:08
User opened query 'Per CDM, DM CLR re-query: Response noted; however there is no procedure recorded to address this AE. Please update this field or record a therapeutic procedure which is within the AE timeframe. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:52:06



US3062167

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query ' Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'has been updated' (Site from DM). DataPoint Verified.	Colton King (b) (4) (b) (4)	08 Feb 2021 20:14:08
User opened query ' Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4)	04 Feb 2021 20:38:45 23 Jan 2021 06:38:57
	Riley King (b) (4) (b) (4)	14 Jan 2021 20:30:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 21:00:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:38:45
User entered 'Subject had a prostatectomy, pain following operation.'	Riley King (b) (4)	14 Jan 2021 20:30:19
	(b) (4)	

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 20:30:19

**US3062167**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Jan 2021 20:30:19

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:37

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User closed query 'please add cephalexin 500mg TID 12/17-12/23 per CM log' (Site from CRA).	(b) (4)	
Query 'please add cephalexin 500mg TID 12/17-12/23 per CM log' answered with 'data corrected' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 21:51:39
User opened query 'please add cephalexin 500mg TID 12/17-12/23 per CM log' (Site from CRA).	Janna Martinez (b) (4)	08 Mar 2021 17:53:12
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 16:40:44
		04 Nov 2020 19:06:04
	Colton King (b) (4)	10 Aug 2020 13:25:43
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:27:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:27:12
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 13:26:37
User entered 'Zolpidem'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Insomnia'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '10'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'mg (mg)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'once daily (QD)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Oral (ORAL)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 11:35:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	10 Aug 2020 13:36:43
answered with 'Correct per protocol ' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:26:36
User entered 'un UNK 2010'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:26:36
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:26:36

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:26:36



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:26:36

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 10:46:52
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	15 Sep 2020 10:46:52
Data point term sent to Coder Coding entries removed.	System marissa Mueller (b) (4)	14 Sep 2020 21:00:23 14 Sep 2020 21:00:19
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:29:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Aug 2020 13:29:22
Data point term sent to Coder User entered 'Meloxicam'	System Colton King (b) (4)	10 Aug 2020 13:28:38 10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User closed query 'Per DM CLR: Please update the CM indication to include the specific location of the OSTEOARTHRITIS (i.e.: Right, left or bilateral knees, hips shoulders, etc.). Update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).		15 Sep 2020 11:45:56
Query 'Per DM CLR: Please update the CM indication to include the specific location of the OSTEOARTHRITIS (i.e.: Right, left or bilateral knees, hips shoulders, etc.). Update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	14 Sep 2020 21:00:23
	(b) (4)	
User entered 'OSTEOARTHRITIS- bilateral hands, shoulders' reason for change: Data Entry Error	marissa Mueller (b) (4)	14 Sep 2020 21:00:19
	(b) (4)	
User opened query 'Per DM CLR: Please update the CM indication to include the specific location of the OSTEOARTHRITIS (i.e.: Right, left or bilateral knees, hips shoulders, etc.). Update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:39:26
Query 'Per CDM, Per DM CLR re-query on MedHis eCRF: Please review Condition and please update to specify the location of Osteoarthritis. Please update and reconcile with MedHis eCRF so there would be an appropriate match.		14 Sep 2020 06:38:55
' canceled (Site from DM).		
User opened query 'Per CDM, Per DM CLR re-query on MedHis eCRF: Please review Condition and please update to specify the location of Osteoarthritis. Please update and reconcile with MedHis eCRF so there would be an appropriate match.		10 Sep 2020 08:54:48
' (Site from DM).		
User entered 'Osteoarthritis'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '15'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'mg (mg)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'once daily (QD)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Oral (ORAL)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
	(b) (4), (b) (6)	11 Aug 2020 11:36:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Colton King (b) (4)	10 Aug 2020 13:36:25
answered with 'Correct per protocol' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:27:56
User entered 'un UNK 2017'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:27:56
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:27:56

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:27:56

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:27:56

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:32:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:32:08
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 13:30:51
User entered 'Metformin'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Type 2 Diabetes Mellitus'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '500'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'mg (mg)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'once daily (QD)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Oral (ORAL)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '01 May 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Oct 2020 15:18:50
	(b) (4)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 11:36:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Correct per protocol ' (Site from System).	Colton King (b) (4)	10 Aug 2020 13:37:09
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:30:09
User entered 'un May 2020'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered '0'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'Yes (Y)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered empty.	Colton King (b) (4) (b) (4)	10 Aug 2020 13:30:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:09:44
User entered 'No (N)'	Colton King (b) (4)	10 Aug 2020 13:30:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:30:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 13:30:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 13:30:09

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:35:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 23:35:57
Data point term sent to Coder	System	25 Nov 2020 23:35:05
User entered 'Sildenafil'	Jeri King (b) (4)	25 Nov 2020 23:34:07

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:12
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:10
Query 'Per DM CLR: Please note that there is no ongoing MH 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 MH or AE eCRF.	(b) (4), (b) (6)	28 Jan 2021 05:59:11
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no ongoing MH 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 MH or AE eCRF.	(b) (4), (b) (6)	28 Jan 2021 05:58:37
' (Site from DM).		
User entered 'Erectile Dysfunction'	Jeri King (b) (4)	25 Nov 2020 23:34:07



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:05
User entered '20'	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:03
User entered 'mg (mg)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:49:01
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:59
User entered 'once daily (QD)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:58
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:56
User entered 'Oral (ORAL)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:54
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:48
User entered '20 Nov 2020'	Jeri King (b) (4)	25 Nov 2020 23:34:07



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:46
User entered '0'	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:44
User entered 'Yes (Y)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:50
User entered empty.	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:52
User entered 'No (N)'	Jeri King (b) (4)	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 23:34:07

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 23:34:07

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 15:11:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 15:11:39
Data point term sent to Coder	System	18 Dec 2020 15:11:05
User entered 'TYLENOL'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:16
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:17
User entered 'covid 19'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:20
User entered '500'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:22
User entered 'mg (mg)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:26
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:28
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:29
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:08
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:07
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:09
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:04
User entered '08 Dec 2020'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:02
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
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)	11 Feb 2021 09:26:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:55
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 'reconciled.' (Site from DM).	Riley King (b) (4)	02 Feb 2021 13:15:45
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:15:34
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).	(b) (4), (b) (6)	23 Jan 2021 06:36:54
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:54
User entered '22 Dec 2020' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:15:34
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:09
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:48:01
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User entered empty.	System	18 Dec 2020 15:10:09

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User entered empty.	System	18 Dec 2020 15:10:09



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:46
User entered empty.	System	18 Dec 2020 15:10:09

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 15:11:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 15:11:04
User entered 'MUCINEX'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:22
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:24
User entered 'covid 19'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:26
User entered '600'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:28
User entered 'mg (mg)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:31
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:33
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:16
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:14
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:12
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:51
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:03
User entered '08 Dec 2020'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:47:01
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
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)	11 Feb 2021 09:26:29
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:57
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 'Reconciled. ' (Site from DM).	Riley King (b) (4)	02 Feb 2021 13:16:10
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:16:03
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).	(b) (4), (b) (6)	23 Jan 2021 06:37:02
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:55
User entered '22 Dec 2020' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:16:03
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:10:51
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:59
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:10:51



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User entered empty.	System	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User entered empty.	System	18 Dec 2020 15:10:51

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:48
User entered empty.	System	18 Dec 2020 15:10:51

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:21:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED PE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 07:42:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 07:42:42
Data point term sent to Coder	System	08 Apr 2021 14:17:13
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	08 Apr 2021 14:16:51
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	08 Apr 2021 14:16:51
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 14:16:36
Coding entries removed.	marissa Mueller (b) (4)	08 Apr 2021 14:16:36
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 14:16:36
User entered 'SUDAFED PE (phenylephrine)' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 14:16:36
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	08 Apr 2021 12:32:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:27

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:53:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 01:53:27
Data point term sent to Coder	System	18 Dec 2020 15:12:06
User entered 'sudafed'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:29
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:31
User entered 'COVID 19'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 12:26:58
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:33
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Correct as entered. ' (Site from DM).	Riley King (b) (4)	02 Feb 2021 13:18:19
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:13:20
User entered '10'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:38
User entered 'mg (mg)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:40
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:24
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:22
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:20
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:18
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:43:56
User entered '08 Dec 2020'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:15
User entered '0'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
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)	11 Feb 2021 09:26:47
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:43:52
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 'Reconciled. ' (Site from DM).	Riley King (b) (4)	02 Feb 2021 13:19:43
User entered 'No (N)' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:18:58
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).	(b) (4), (b) (6)	23 Jan 2021 06:37:15
User entered 'Yes (Y)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:43:54
User entered '22 Dec 2020' reason for change: New Information	Riley King (b) (4)	02 Feb 2021 13:18:58
User entered empty.	marissa Mueller (b) (4)	18 Dec 2020 15:11:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:46:13
User entered 'No (N)'	marissa Mueller (b) (4)	18 Dec 2020 15:11:11

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User entered empty.	System	18 Dec 2020 15:11:11

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User entered empty.	System	18 Dec 2020 15:11:11

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:39:53
User entered empty.	System	18 Dec 2020 15:11:11

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:22
	(b) (4)	
User closed query 'Per CDM CLR(RQ) : Thanks for your response. Kindly note Name of medication field must contain only the medication name and the dosage (eg :5/325 MG) will be recorded in the Dose and Dose unit .Kindly check and make updates' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:09:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 14:17:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 14:17:13
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 14:16:03
Query 'Per CDM CLR(RQ) : Thanks for your response. Kindly note Name of medication field must contain only the medication name and the dosage (eg :5/325 MG) will be recorded in the Dose and Dose unit .Kindly check and make updates' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	15 Apr 2021 14:15:57
DataPoint Un-verified.	(b) (4)	
	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
Coding entries removed.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
User entered 'NORCO' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per CDM CLR(RQ) : Thanks for your response. Kindly note Name of medication field must contain only the medication name and the dosage (eg :5/325 MG) will be recorded in the Dose and Dose unit .Kindly check and make updates' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:11:32
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325 MG) from the medication name field as this should be recorded in the Dose and Units field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:09:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325 MG) from the medication name field as this should be recorded in the Dose and Units field. Update eCRF as appropriate.' answered with 'please, clarify as previous requests have been to document combo meds this way' (Site from DM).	(b) (4) marissa Mueller (b) (4)	02 Apr 2021 20:08:58
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325 MG) from the medication name field as this should be recorded in the Dose and Units field. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:44:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:21:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:21:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
Data point term sent to Coder	System	17 Mar 2021 16:43:27
DataPoint Un-verified.	Sherry Henning (b) (4)	17 Mar 2021 16:43:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Sherry Henning (b) (4)	17 Mar 2021 16:43:13
User entered 'NORCO (5/325 mg)' reason for change: Data Entry Error	(b) (4)	
User entered 'NORCO (5/325 mg)' reason for change: Data Entry Error	Sherry Henning (b) (4)	17 Mar 2021 16:43:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 10:46:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 20:08:44
Coding entries removed.	Colton King (b) (4)	08 Feb 2021 20:08:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 20:45:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:25:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 13:19:46
Coding entries removed.	Riley King (b) (4)	02 Feb 2021 13:19:27
	(b) (4)	
User entered 'NORCO 5/325' reason for change: Data Entry Error	Riley King (b) (4)	02 Feb 2021 13:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 20:33:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 20:33:58
Data point term sent to Coder	System	14 Jan 2021 20:33:28
User entered 'Norco'	Riley King (b) (4)	14 Jan 2021 20:32:53

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:36
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:29:33
User closed query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:27:41
Query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Colton King (b) (4)	08 Feb 2021 20:08:48
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	08 Feb 2021 20:08:40
	(b) (4)	
User entered 'POST OPERATIVE PAIN Generalized' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 20:08:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 20:45:34
User opened query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:28:47
User entered 'Post operative pain'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:22
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
User entered '5/325' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:33
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	02 Feb 2021 13:19:27
	(b) (4)	
User entered '5/235'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:19:22
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Apr 2021 14:15:20
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:31
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Riley King (b) (4)	02 Feb 2021 13:19:27
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:29
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:27
User entered 'as needed (PRN)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:25
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:23
User entered 'Oral (ORAL)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:20
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:19
User entered '9 Jan 2021'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:17
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:15
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:13
User entered '11 Jan 2021'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:12
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:32:53
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User entered empty.	System	14 Jan 2021 20:32:53

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User entered empty.	System	14 Jan 2021 20:32:53

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:40:59
User entered empty.	System	14 Jan 2021 20:32:53

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Feb 2021 23:39:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 23:39:45
Data point term sent to Coder	System	08 Feb 2021 20:07:34
Coding entries removed.	Colton King (b) (4)	08 Feb 2021 20:07:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:44:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:54:58
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 Jan 2021 21:54:58
Data point term sent to Coder	System	14 Jan 2021 20:33:28
User entered 'Aleve'	Riley King (b) (4) (b) (4)	14 Jan 2021 20:33:27

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:29
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:30:02
User closed query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:27:45
Query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Colton King (b) (4)	08 Feb 2021 20:07:39
	(b) (4)	
DataPoint Un-verified.	Colton King (b) (4)	08 Feb 2021 20:07:21
	(b) (4)	
User entered 'POST OPERATIVE PAIN Generalized' reason for change: Data Entry Error	Colton King (b) (4)	08 Feb 2021 20:07:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 20:44:28
User opened query 'Per DM CLR: Please update the indication to reflect the location of POST OPERATIVE PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:29:04
User entered 'Post operative pain'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:50
User entered '600'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:52
User entered 'mg (mg)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:54
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:55
User entered 'as needed (PRN)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:57
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:38
User entered 'Oral (ORAL)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:40
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:36
User entered '11 Jan 2021'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:42
User entered '0'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	08 Mar 2021 17:24:11
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:51
DataPoint Verified.		04 Feb 2021 20:44:44
User entered 'Yes (Y)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Richard Glover (b) (4)	23 Apr 2021 15:53:26
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	19 Apr 2021 18:35:55
	(b) (4)	
Signature has been broken.	Riley King (b) (4)	19 Apr 2021 18:35:55
	(b) (4)	
User entered '14 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	19 Apr 2021 18:35:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'please verify as 30Jan21 as per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 18:01:41
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
Query 'please verify as 30Jan21 as per CM log' answered with 'DATA CORRECTED' (Site from CRA).	Janna Martinez (b) (4)	08 Mar 2021 17:24:20
	(b) (4)	
User entered '30 Jan 2021' reason for change: Data Entry Error	Janna Martinez (b) (4)	08 Mar 2021 17:24:11
	(b) (4)	
User opened query 'please verify as 30Jan21 as per CM log' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 16:31:22
DataPoint Un-verified.		04 Feb 2021 20:45:54
DataPoint Verified.		04 Feb 2021 20:44:45
User entered empty.	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:44:47
User entered 'No (N)'	Riley King (b) (4)	14 Jan 2021 20:33:27
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User entered empty.	System	14 Jan 2021 20:33:27

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User entered empty.	System	14 Jan 2021 20:33:27

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:10
User entered empty.	System	14 Jan 2021 20:33:27

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEF RADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Feb 2021 17:44:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Feb 2021 17:44:44
Data point term sent to Coder	System	15 Feb 2021 17:44:22
User entered 'Ancef'	Riley King (b) (4)	15 Feb 2021 17:44:01

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:31
User entered 'Yes (Y)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:27
User entered 'infection prophylaxis'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:33
User entered '2'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:35
User entered 'g (g)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:39
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:41
User entered 'once (ONCE)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:45
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:47
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:50
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:52
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:56
User entered '0'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:20:57
User entered 'No (N)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:05
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:21:09
User entered 'No (N)'	Riley King (b) (4)	15 Feb 2021 17:44:01
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User entered empty.	System	15 Feb 2021 17:44:01

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User entered empty.	System	15 Feb 2021 17:44:01

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:18
User entered empty.	System	15 Feb 2021 17:44:01

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 17:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 17:47:50
Data point term sent to Coder	System	15 Feb 2021 17:47:36
User entered 'Heparin'	Riley King (b) (4)	15 Feb 2021 17:47:17



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:05
User entered 'Yes (Y)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:07
User entered 'Deep vein thrombosis prophylaxis'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:02:02
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	17 Mar 2021 15:38:09
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	17 Mar 2021 15:38:00
	(b) (4)	
User entered '5000' reason for change: Data Entry Error	Riley King (b) (4)	17 Mar 2021 15:38:00
	(b) (4)	
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 11:36:13
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:09
User entered '30'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
DataPoint Un-verified.	Riley King (b) (4)	17 Mar 2021 15:38:00
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 15:38:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:11
User entered 'mg (mg)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:14
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:15
User entered 'once (ONCE)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:17
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:19
User entered 'Subcutaneous (SUBCUTANEOUS)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:22
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:23
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:25
User entered '0'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:27
User entered 'No (N)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:29
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:38:31
User entered 'No (N)'	Riley King (b) (4)	15 Feb 2021 17:47:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User entered empty.	System	15 Feb 2021 17:47:17

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User entered empty.	System	15 Feb 2021 17:47:17



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:29
User entered empty.	System	15 Feb 2021 17:47:17

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEFALOXIN [CEFALOXIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Mar 2021 17:39:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 17:38:35
User entered 'CEFALOXIN'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'Yes (Y)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'INFECTION PROPHYLAXIS'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '500'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'mg (mg)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'three times daily (TID)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	



US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '17 Jan 2021'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '0'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'No (N)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '23 Jan 2021'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'No (N)'	Janna Martinez (b) (4)	08 Mar 2021 17:38:17
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User entered '3'	System	08 Mar 2021 17:38:17

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User entered '1'	System	08 Mar 2021 17:38:17

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:41:40
User entered '804 (804)'	System	08 Mar 2021 17:38:17

US3062167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 16:50:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 16:50:52
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 16:49:38
User entered 'cialis'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'No (N)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'erectile dysfunction'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '20' reason for change: Data Entry Error	Sherry Henning (b) (4)	17 Mar 2021 17:09:55
	(b) (4)	
User entered '2'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'mg (mg)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'once daily (QD)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '02 Mar 2021'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered '0'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'Yes (Y)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	



**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered empty.	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:15:16
User entered 'No (N)'	Sherry Henning (b) (4)	17 Mar 2021 16:49:19
	(b) (4)	

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 16:49:19

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 16:49:19

**US3062167**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 16:49:19

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:59:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User closed query 'Per CDM, per DM CLR re-query on AE #1: Please note that there was a query which was NOT asking the site to delete the DIAGNOSTIC procedure previously recorded on the Con Proc page (Prostate biopsy). Please review and update the ConMed page to record all concomitant procedures. The query was asking if there was a THERAPEUTIC procedure performed for AE#1. If not, then the Concomitant Procedure field on AE#1 should not be ticked. Please review and update Con Proc and AE#1 pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:13:46
Query 'Per CDM, per DM CLR re-query on AE #1: Please note that there was a query which was NOT asking the site to delete the DIAGNOSTIC procedure previously recorded on the Con Proc page (Prostate biopsy). Please review and update the ConMed page to record all concomitant procedures. The query was asking if there was a THERAPEUTIC procedure performed for AE#1. If not, then the Concomitant Procedure field on AE#1 should not be ticked. Please review and update Con Proc and AE#1 pages as appropriate.' answered with 'added back. pending records' (Site from DM).	marissa Mueller (b) (4)	05 Dec 2020 01:58:34
User opened query 'Per CDM, per DM CLR re-query on AE #1: Please note that there was a query which was NOT asking the site to delete the DIAGNOSTIC procedure previously recorded on the Con Proc page (Prostate biopsy). Please review and update the ConMed page to record all concomitant procedures. The query was asking if there was a THERAPEUTIC procedure performed for AE#1. If not, then the Concomitant Procedure field on AE#1 should not be ticked. Please review and update Con Proc and AE#1 pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:12:11
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 14:42:24

**US3062167**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 14:59:37**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jeri King (b) (4)	02 Nov 2020 23:11:46
User entered 'No (N)'	Brianna Burton (b) (4)	02 Sep 2020 14:31:33

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:23
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:59:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Dec 2020 01:59:03
User entered '16 Oct 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	05 Dec 2020 01:59:03
	(b) (4)	
DataPoint activated with code reason code Data required.	marissa Mueller (b) (4)	05 Dec 2020 01:58:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	25 Nov 2020 23:39:24
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:38:55
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:38:55
User entered empty; reason for change Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:38:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:08:40
User entered '16 Oct 2020'	Jeri King (b) (4)	02 Nov 2020 23:12:32



US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:46:51
User closed query 'please correct spelling to biopsy' (Site from CRA).		11 Feb 2021 18:46:44
Query 'please correct spelling to biopsy' answered with 'UPDATED' (Site from CRA).	Colton King (b) (4)	08 Feb 2021 20:10:48
User entered 'PROSTATE BIOPSY' reason for change: Data Entry Error	(b) (4)	08 Feb 2021 20:10:43
User opened query 'please correct spelling to biopsy' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:40:16
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:59:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Dec 2020 01:59:03
User entered 'prostate viopsy' reason for change: Data Entry Error	marissa Mueller (b) (4)	05 Dec 2020 01:59:03
	(b) (4)	
DataPoint activated with code reason code Data required.	marissa Mueller (b) (4)	05 Dec 2020 01:58:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	25 Nov 2020 23:39:24
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:38:55
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:38:55
User entered empty; reason for change Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:38:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:08:40
User entered 'Prostate biopsy'	Jeri King (b) (4)	02 Nov 2020 23:12:32

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:19
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:59:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Dec 2020 01:59:03
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	marissa Mueller (b) (4)	05 Dec 2020 01:59:03
	(b) (4)	
DataPoint activated with code reason code Data required.	marissa Mueller (b) (4)	05 Dec 2020 01:58:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	25 Nov 2020 23:39:24
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:38:55
DataPoint Un-verified.	Jeri King (b) (4)	25 Nov 2020 23:38:55
User entered empty; reason for change Data Entry Error	Jeri King (b) (4)	25 Nov 2020 23:38:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:08:40
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	02 Nov 2020 23:12:32

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint activated with code reason code Data required.	marissa Mueller (b) (4)	05 Dec 2020 01:58:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jeri King (b) (4)	25 Nov 2020 23:39:24
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:08:40
User entered empty.	Jeri King (b) (4)	02 Nov 2020 23:12:32

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:31
User entered '8 Jan 2021'	Riley King (b) (4)	14 Jan 2021 21:25:17
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 16:19:13
DataPoint Un-verified.	Riley King (b) (4)	15 Feb 2021 17:50:48
	(b) (4)	
User entered 'robotic assisted laparoscopic radical PROSTATECTOMY' reason for change: Data Entry Error	Riley King (b) (4)	15 Feb 2021 17:50:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:32
User entered 'Prostatectomy'	Riley King (b) (4)	14 Jan 2021 21:25:17
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:34
User entered 'Adverse Event (AE)'	Riley King (b) (4)	14 Jan 2021 21:25:17
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:40:36
User entered empty.	Riley King (b) (4)	14 Jan 2021 21:25:17
	(b) (4)	

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:51:30
	(b) (4)	



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'Bilateral pelvic lymphadenectomy'	Riley King (b) (4)	15 Feb 2021 17:51:30
	(b) (4)	

**US3062167**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'Adverse Event (AE)'	Riley King (b) (4)	15 Feb 2021 17:51:30
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:51:30
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered '8 Jan 2021'	Riley King (b) (4)	15 Feb 2021 17:51:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'suprapubic tube placement'	Riley King (b) (4)	15 Feb 2021 17:51:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'Adverse Event (AE)'	Riley King (b) (4)	15 Feb 2021 17:51:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered empty.	Riley King (b) (4)	15 Feb 2021 17:51:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
User closed query 'Per DM CLR: Please review if this was done for AE# 1 Prostate Cancer. If so, please note that the Date of this procedure/Surgery is out of the expected timeframe with the AE (16 OCT 2020 - 8 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:05:55
Query 'Per DM CLR: Please review if this was done for AE# 1 Prostate Cancer. If so, please note that the Date of this procedure/Surgery is out of the expected timeframe with the AE (16 OCT 2020 - 8 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Changed to diagnostic ' (Site from DM).	Riley King (b) (4)	17 Mar 2021 20:09:02
User opened query 'Per DM CLR: Please review if this was done for AE# 1 Prostate Cancer. If so, please note that the Date of this procedure/Surgery is out of the expected timeframe with the AE (16 OCT 2020 - 8 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:15:01
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered '10 Aug 2020'	Riley King (b) (4)	02 Mar 2021 14:58:35



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'PSA level'	Riley King (b) (4)	02 Mar 2021 14:58:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	17 Mar 2021 20:08:48
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Riley King (b) (4)	17 Mar 2021 20:08:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'Adverse Event (AE)'	Riley King (b) (4)	02 Mar 2021 14:58:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered empty.	Riley King (b) (4)	02 Mar 2021 14:58:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered '16 Oct 2020'	Riley King (b) (4)	02 Mar 2021 15:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'transrectal ultrasound of the prostate'	Riley King (b) (4)	02 Mar 2021 15:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered 'Adverse Event (AE)'	Riley King (b) (4)	02 Mar 2021 15:00:11
	(b) (4)	

US3062167

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:25:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:16:50
User entered empty.	Riley King (b) (4)	02 Mar 2021 15:00:11
	(b) (4)	

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered	System	03 Nov 2020 18:41:06
'USA-US090-2020-MRNA-1273-P301000007'		



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
User entered '03/Nov/2020 18:42'	System	03 Nov 2020 18:42:22



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'I'		03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '23/Nov/2020 15:20'	System	23 Nov 2020 20:20:44

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
Reviewed for Safety.		30 Nov 2020 20:38:10
User entered 'I'		23 Nov 2020 20:20:44

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '30/Nov/2020 20:38'	System	30 Nov 2020 20:38:22

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
Reviewed for Safety.		15 Jan 2021 13:53:41
User entered 'I'		30 Nov 2020 20:38:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '07/Dec/2020 13:04'	System	07 Dec 2020 18:04:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
Reviewed for Safety.		15 Jan 2021 13:53:41
User entered 'I'		07 Dec 2020 18:04:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '15/Jan/2021 08:53'	System	15 Jan 2021 13:53:50



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
Reviewed for Safety.		22 Jan 2021 16:51:03
User entered 'I'		15 Jan 2021 13:53:50

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered	System	03 Nov 2020 18:41:06
'USA-US090-2020-MRNA-1273-P301000007'		

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '02/Mar/2021 14:21'	System	02 Mar 2021 20:21:25

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 20:21:25

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'USA-US090-2020-MRNA-1273-P301000007'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:04:00
DataPoint Un-verified.		04 Nov 2020 19:03:18
DataPoint Verified.		04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'No (N)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Yes (Y)'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Richard'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered 'Glover'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '700 Medical Center Dr.'	System	03 Nov 2020 18:41:06

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered 'Newton'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:02:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:42:03
User entered 'KS'	System	03 Nov 2020 18:41:06



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:03:00
Reviewed for Safety.		03 Nov 2020 18:42:03
User entered '67114'	System	03 Nov 2020 18:41:06

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:20:13
DataPoint Verified.		04 Nov 2020 19:03:00
User entered 'US'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 20:21:25
User entered '6'	System	02 Mar 2021 20:21:25
User entered '5'	System	15 Jan 2021 13:53:50
User entered '4'	System	07 Dec 2020 18:04:06
User entered '3'	System	30 Nov 2020 20:38:22
User entered '2'	System	23 Nov 2020 20:20:44
User entered '1'	System	03 Nov 2020 18:42:22

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered '02/Mar/2021 14:21'	System	02 Mar 2021 20:21:25

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:12:59
User entered 'I'		02 Mar 2021 20:21:25

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:52:14
User entered	System	21 Dec 2020 15:51:39
'USA-US090-2020-MRNA-1273-P301000014'		

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Richard'	System	21 Dec 2020 15:51:39

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Glover'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:52:14
User entered '700 Medical Center Dr.'	System	21 Dec 2020 15:51:39



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Newton'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'KS'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '67114'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		13 Jan 2021 21:31:53
User entered 'US'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Mar 2021 20:07:05
User entered '2'	System	13 Jan 2021 21:32:05
User entered '1'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'USA-US090-2020-MRNA-1273-P301000014'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Richard'	System	21 Dec 2020 15:51:39

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Glover'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '700 Medical Center Dr.'	System	21 Dec 2020 15:51:39



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Newton'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'KS'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '67114'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		13 Jan 2021 21:31:53
User entered 'US'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Mar 2021 20:07:05
User entered '2'	System	13 Jan 2021 21:32:05
User entered '1'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
User entered '21/Dec/2020 10:52'	System	21 Dec 2020 15:52:26

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		13 Jan 2021 21:31:53
User entered 'I'		21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'USA-US090-2020-MRNA-1273-P301000014'	System	21 Dec 2020 15:51:39



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:52:14
User entered 'Richard'	System	21 Dec 2020 15:51:39



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Glover'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '700 Medical Center Dr.'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Newton'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'KS'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '67114'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		13 Jan 2021 21:31:53
User entered 'US'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Mar 2021 20:07:05
User entered '2'	System	13 Jan 2021 21:32:05
User entered '1'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
User entered '13/Jan/2021 21:32'	System	13 Jan 2021 21:32:05



US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		06 Mar 2021 20:06:56
User entered 'I'		13 Jan 2021 21:32:05

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'USA-US090-2020-MRNA-1273-P301000014'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'No (N)'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Richard'	System	21 Dec 2020 15:51:39

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Glover'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '700 Medical Center Dr.'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'Newton'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered 'KS'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		21 Dec 2020 15:52:14
User entered '67114'	System	21 Dec 2020 15:51:39

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
Reviewed for Safety.		13 Jan 2021 21:31:53
User entered 'US'	System	21 Dec 2020 15:52:26



**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Mar 2021 20:07:05
User entered '2'	System	13 Jan 2021 21:32:05
User entered '1'	System	21 Dec 2020 15:52:26

**US3062167**

**Folder: SAE USA-US090-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
User entered '06/Mar/2021 15:07'	System	06 Mar 2021 20:07:05

US3062167

Folder: SAE USA-US090-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:37

**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.	Troy Holdeman (b) (4)	02 Apr 2021 20:41:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:09:52
User entered 'I'		06 Mar 2021 20:07:05