

US3612031 (Prod: University of Texas- Galveston)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:00:48

All time stamps listed in this document are displayed in GMT

US3612031

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 16:53:35

Generated On: 11 Aug 2021 23:00:48

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[Participant ID](#)

US3612031

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

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US3612031

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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) 05 Mar 2021 20:05:15

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 20:05:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 20:05:15

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 20:05:15

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Condition	OSTEOARTHRITIS OF KNEES
Start date (dd MMM yyyy)	UN OCT 2008
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)	OCT 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:05:15

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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> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:04 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:04
Height ( <i>xxx.x</i> )	68 in
Weight ( <i>xxx.x</i> )	220.0 lb
BMI ( <i>xxx.x</i> )	33.52083 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) 05 Mar 2021 20:05:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 20:05:15

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

(b) (6) CLUB MEETINGS WITH OTHER MEMBERS FREQUENTLY.

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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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 20:05:15

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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) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190300

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 20:05:15

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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) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:04
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	21 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:22 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:22
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 10:49

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) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

10 SEP 2020 09:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Collection date ( <i>dd MMM yyyy</i> )			10 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:56	10 SEP 2020 09:56
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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: 11 Aug 2021 23:00:48

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 11:19

PC Open Date & Time

10 SEP 2020 11:09

PC Close Date & Time

10 SEP 2020 13:39

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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 97.6 °F

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

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

PC Time Stamp	10 SEP 2020 20:34
PC Open Date & Time	10 SEP 2020 14:34
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 SEP 2020 12:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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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

95.3 °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

15 SEP 2020 06:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

15 SEP 2020 19:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

16 SEP 2020 12:32

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**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

10 SEP 2020 11:20

PC Open Date & Time

10 SEP 2020 11:09

PC Close Date & Time

10 SEP 2020 13:39

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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

10 SEP 2020 20:34

PC Open Date & Time

10 SEP 2020 14:34

PC Close Date & Time

11 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**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

11 SEP 2020 12:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**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

12 SEP 2020 12:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**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

13 SEP 2020 12:11

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**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

15 SEP 2020 06:17

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

**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

15 SEP 2020 19:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**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

16 SEP 2020 12:32

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**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 ☐

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

No ☐

Yes ☒

PC Time stamp	10 SEP 2020 11:22
PC Open Date & Time	10 SEP 2020 11:09
PC Close Date & Time	10 SEP 2020 13:39

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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 ☐

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 20:34
PC Open Date & Time	10 SEP 2020 14:34
PC Close Date & Time	11 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**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 ☒

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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 ☒

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:17
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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 ☒

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EAB) (1725)

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:04
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3612031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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)	06 OCT 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 12:00
Temperature (xxx.x)	098.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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)	06 OCT 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 13:18
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

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) 6 OCT 2020

What was the treatment time? (00:00-23:59) 12:41 (24 HR)

Treatment Date and Time (derived) 6 OCT 2020 12:41

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

US3612031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	06 OCT 2020 12:15

US3612031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:21	06 OCT 2020 12:21
Nasopharyngeal Swab 2	No		

US3612031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**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

98.1 °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

06 OCT 2020 13:26

PC Open Date & Time

06 OCT 2020 13:01

PC Close Date & Time

06 OCT 2020 15:31

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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 95.2 °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	06 OCT 2020 22:31
PC Open Date & Time	06 OCT 2020 16:26
PC Close Date & Time	07 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

07 OCT 2020 12:09

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 OCT 2020 12:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 13:47

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**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

97.4 °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 OCT 2020 12:54

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

**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

97.7 °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

11 OCT 2020 16:20

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 OCT 2020 12:02

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**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

06 OCT 2020 13:27

PC Open Date & Time

06 OCT 2020 13:01

PC Close Date & Time

06 OCT 2020 15:31

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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

06 OCT 2020 22:31

PC Open Date & Time

06 OCT 2020 16:26

PC Close Date & Time

07 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**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

07 OCT 2020 12:09

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**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

08 OCT 2020 12:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**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

09 OCT 2020 13:47

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**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

10 OCT 2020 12:54

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

**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

11 OCT 2020 16:20

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**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

12 OCT 2020 12:02

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**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 ☐

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 13:27
PC Open Date & Time	06 OCT 2020 13:01
PC Close Date & Time	06 OCT 2020 15:31

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**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 ☐

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 22:32
PC Open Date & Time	06 OCT 2020 16:26
PC Close Date & Time	07 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**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 ☒

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:10
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:25
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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 ☒

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 13:48
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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 ☒

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 12:55
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 16:21
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**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 ☒

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 12:03
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3612031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3612031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 08:40
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	099 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	020 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 NOV 2020

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

US3612031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 NOV 2020

Collection time (00:00-23:59)

08:51 (24 HR)

Collection date and time (derived)

02 NOV 2020 08:51

US3612031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 NOV 2020 12:04:05
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	17 NOV 2020 17:11:31
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	21 NOV 2020 11:51:08
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

<b>TIMEPOINT</b>	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 13:08:32
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 19:59:15

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 20:21:24
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 16:50:05

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 08:32:58
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 07:40:57
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 04:23:40
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 10:38:28
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

25 JAN 2021 15:03:33

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

31 JAN 2021 12:54:44

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

08 FEB 2021 18:10:18

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 15:46:51
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☒

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 13:43:45

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

01 MAR 2021 12:02:33

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 07:28:33
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 16:20:52
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

23 MAR 2021 12:25:20

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 20:02:29
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

03 APR 2021 16:09:17

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 APR 2021 18:17:34

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

18 APR 2021 19:44:16

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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

27 APR 2021 10:22:54

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 08:31:18
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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 <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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐ 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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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27 OCT 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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 <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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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°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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐  
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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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="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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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31 AUG 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 SEP 2022 00:01

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07 SEP 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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14 SEP 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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21 SEP 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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28 SEP 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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01 OCT 2022 00:01

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05 OCT 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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12 OCT 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

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**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

**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 ☐

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3612031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

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"/>

**US3612031**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3612031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:00:48

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		01 MAR 2021 12:02:45

US3612031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:05:15

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3612031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3612031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

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.*

US3612031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

09:18 (24 HR)

Collection date and time (derived)

30 MAR 2021 09:18

US3612031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3612031**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

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*

**US3612031**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Date of Contact	28 DEC 2020
Time of Contact	13:40
Date and Time of Contact (derived)	28 DEC 2020 13:40
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input 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>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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"/>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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"/>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	098.7 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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Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

Date	30 DEC 2020
------	-------------

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

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

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

Temperature	98.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

Date	31 DEC 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	99.8 F
-------------	--------

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

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input 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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 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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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 JAN 2021	
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 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 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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Form: Symptom Log (8)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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	3 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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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Form: Symptom Log (9)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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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Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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 28 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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	4 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (10)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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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Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

Date	05 JAN 2021
------	-------------

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 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 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	097.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Mar 2021 16:45:34

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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"/>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

	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"/>

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Date of Visit	28 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:29:50

Generated On: 11 Aug 2021 23:00:48

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 \_\_\_\_\_ 31 DEC 2020

End Date \_\_\_\_\_ 31 DEC 2020

Oxygen Saturation \_\_\_\_\_ 93 %

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 \_\_\_\_\_

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:29:50

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:29:50

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed: (b) (4) 29 Mar 2021 16:45:35**

**Generated On: 11 Aug 2021 23:00:48**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 DEC 2020
Day 5	Yes	30 DEC 2020
Day 7	Yes	01 JAN 2021
Day 9	Yes	03 JAN 2021
Day 14	Yes	08 JAN 2021
Day 21	Yes	15 JAN 2021
Day 28	Yes	22 JAN 2021

US3612031

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3612031

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 13:49
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	098.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	091 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612031

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3612031

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:02
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 JAN 2021

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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

Visit date (dd MMM yyyy)	29 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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US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Date of updated informed consent ( <i>dd MMM yyyy</i> )	29 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> )	29 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

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	29 JAN 2021
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 10:37
Temperature (xxx.x)	098.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	093 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	29 JAN 2021
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 11:17
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	089 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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.*

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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) 29 JAN 2021

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 29 JAN 2021 10:45

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

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

10:10 (24 HR)

Collection date and time (derived)

29 JAN 2021 10:10

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	10:14
Collection Date and Time (derived)	29 JAN 2021 10:14

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3612031

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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)	10:18 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 10:18
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	075 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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)	11:07 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:07
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	079 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG

US3612031

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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.*

US3612031

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

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) 10:35 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3612031

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:35

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Data signed: (b) (4) 29 Mar 2021 16:45:36**

**Generated On: 11 Aug 2021 23:00:48**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3612031

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:45:36

Generated On: 11 Aug 2021 23:00:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3612031

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3612031

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

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) 31 Mar 2021 21:10:46

Generated On: 11 Aug 2021 23:00:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

09:18 (24 HR)

Collection date and time (derived)

30 MAR 2021 09:18

US3612031

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 16:14:38

Generated On: 11 Aug 2021 23:00:48

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3612031

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

AEID

Adverse event

SINUS INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

US3612031

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

AEID	
Adverse event	WHEEZING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 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)	09 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

AEID	USA-US129-2021-MRNA-1273-P30 1000003
Adverse event	SMPTOMATIC 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)	26 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)	08 JAN 2021
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 (6)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (7)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

AEID	
Adverse event	TACHYCARDIA
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)	12 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

AEID	
Adverse event	NECK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 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 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication INDOMETHACIN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS OF  
BILATERAL KNEES

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify \_\_\_\_\_

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 SEP 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 (2)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication BACTRIM

Prophylaxis Yes ☐  
No ☒

Indication SINUS INFECTION

Dose per administration 800/160

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SINUS INFECTION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
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 (4)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication WHEEZING

Dose per administration 90

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) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐  
No ☒

Indication WHEEZING

Dose per administration 4

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 (5)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	7 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication ACETAMINOPHEN/ASPIRIN/CAF  
FEINE

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID19

Dose per administration 325/500/65

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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US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)	26 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)	05 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication NECK PAIN

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☒  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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 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)	13 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)	16 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication TACHYCARDIA

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication TACHYCARDIA

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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)		12 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 5000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☒  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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) 13 Apr 2021 13:21:42

Generated On: 11 Aug 2021 23:00:48

	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 type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 FEB 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"/>

US3612031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Mar 2021 16:45:34

Generated On: 11 Aug 2021 23:00:48

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3612031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:00:48

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

US3612031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:00:48

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 ☐

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

SAEID	USA-US129-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	
Site Address: City	
Site Address: State	TEXAS
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

SAEID	USA-US129-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	
Site Address: City	
Site Address: State	TEXAS
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/JAN/2021 12:37
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.	True

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

SAEID	USA-US129-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	
Site Address: City	
Site Address: State	TEXAS
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 16:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 14:56:01

Generated On: 11 Aug 2021 23:00:48

SAEID	USA-US129-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	RUPP
Site Address: Street	
Site Address: City	
Site Address: State	TEXAS
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/MAR/2021 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3612031 (Prod: University of Texas- Galveston)

**US3612031**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 23:00:48**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:53:35
User closed query 'Patient has 3 AEs in source, please consider adding to EDC. ' (Site from CRA).	(b) (4)	30 Sep 2020 15:32:59
Query 'Patient has 3 AEs in source, please consider adding to EDC. ' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	
	Amy McMahan (b) (4)	28 Sep 2020 21:58:10
	(b) (4)	
User opened query 'Patient has 3 AEs in source, please consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:53:42
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:42:28
	(b) (4), (b) (6)	
User entered 'US3612031'	RWS_ENDPOINT	10 Sep 2020 14:34:31
	ENDPOINT (b) (4)	
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:07
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:18
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:07
User entered '10 SEP 2020'	RWS_ENDPOINT	10 Sep 2020 14:34:32
	ENDPOINT (b) (4)	
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[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 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:07
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:18
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'SCRN'	System	10 Sep 2020 14:37:18

US3612031

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:48

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered (b) (6) 1953'	RWS_ENDPOINT	10 Sep 2020 14:34:33
	ENDPOINT (b) (4)	
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '67'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'YEARS'	System	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered '67'	System	10 Sep 2020 14:37:44

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered 'Male (M)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:31
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered 'I'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:37:31
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:37:31
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:37:31
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:37:31
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:48**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:43:12
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:31

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered '10 Sep 2020'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:37:44

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'Sep 2020'	System	10 Sep 2020 14:37:44

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered '2020'	System	10 Sep 2020 14:37:44

US3612031

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Patient enrolled after protocol Amd. 3 approval date for site, 24Aug2020. Please review and reconcile.' (Site from CRA).	(b) (4)	30 Sep 2020 15:33:56
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:33:54
Query 'Patient enrolled after protocol Amd. 3 approval date for site, 24Aug2020. Please review and reconcile.' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 22:00:01
User entered 'Amendment 3 (3)' reason for change:	(b) (4)	28 Sep 2020 21:59:57
Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:44:07
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 16:44:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:43:56
User opened query 'Patient enrolled after protocol Amd. 3 approval date for site, 24Aug2020. Please review and reconcile.' (Site from CRA).	Amy McMahan (b) (4)	10 Sep 2020 14:37:44
User entered 'Amendment 2 (2)'	(b) (4)	

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**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:44
	(b) (4)	

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**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:37:44
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:37:44
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:44
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:05
User entered empty.	RWS_ENDPOINT	10 Sep 2020 14:34:32
	ENDPOINT (b) (4)	
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:48**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'I'	System	10 Sep 2020 14:37:50

**US3612031**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 23:00:48**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:33
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:37:50
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 23:00:48**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:39
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:38:08
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:16:53
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per DM CLR RQ: Response to previous query noted as 'updated term'. However, the type of Arthritis (Rheumatoid versus Osteoarthritis) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:45:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 18:26:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 18:26:18
Data point term sent to Coder	System	26 Oct 2020 17:29:44
Query 'Per DM CLR RQ: Response to previous query noted as 'updated term'. However, the type of Arthritis (Rheumatoid versus Osteoarthritis) was not specified. Please review and update medical history eCRF as appropriate.' answered with 'Updated' (Site from DM).	Amber Stanford (b) (4)	26 Oct 2020 17:29:24
Coding entries removed.	Amber Stanford (b) (4)	26 Oct 2020 17:29:20
User entered 'OSTEOARTHRITIS OF KNEES' reason for change: Data Entry Error	Amber Stanford (b) (4)	26 Oct 2020 17:29:20
User opened query 'Per DM CLR RQ: Response to previous query noted as 'updated term'. However, the type of Arthritis (Rheumatoid versus Osteoarthritis) was not specified. Please review and update medical history eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 08:22:58
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:27:04

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:48

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:14:47
Data point term sent to Coder	System	21 Oct 2020 22:14:25
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 22:13:57
' answered with 'updated term' (Site from DM). DataPoint Un-verified.	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 22:13:41
Coding entries removed.	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 22:13:41
User entered 'ARTHRITIS of Knees' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	21 Oct 2020 22:13:41
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable	(b) (4), (b) (6)	21 Oct 2020 15:08:10
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:44:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:39:42
Data point term sent to Coder	System	10 Sep 2020 14:38:52
User entered 'ARTHRITIS'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:38:40

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per source start date is Unk Oct 2008. Please review and reconcile as needed. ' (Site from CRA).	(b) (4)	30 Sep 2020 15:34:12
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:34:10
Query 'Per source start date is Unk Oct 2008. Please review and reconcile as needed. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 22:00:42
User entered 'UN Oct 2008' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 22:00:37
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 16:45:23
User opened query 'Per source start date is Unk Oct 2008. Please review and reconcile as needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:45:21
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:44:44
User entered 'UN UNK 2008'	Amy McMahan (b) (4)	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:44:44
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:44:44
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:38:40
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:44:44
User entered empty.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:44:44
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'Oct 2008'	System	28 Sep 2020 22:00:37
User entered 'Jan 2008'	System	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered '2008'	System	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered empty.	System	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered empty.	System	10 Sep 2020 14:38:40

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered '09:04'	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered '10 Sep 2020 09:04'	System	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered '68' in	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
DataPoint set to visible.	(b) (4)	
	System	10 Sep 2020 14:37:50

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered '220.0' lb	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
DataPoint set to visible.	(b) (4)	
	System	10 Sep 2020 14:37:50

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered '33.52083'	System	10 Sep 2020 14:39:13
DataPoint set to visible.	System	10 Sep 2020 14:37:50

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'kg/m2'	System	10 Sep 2020 14:39:13
DataPoint set to visible.	System	10 Sep 2020 14:37:50

US3612031

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:39:13
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered empty.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'bpm'	System	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'breaths/min'	System	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'mmHg'	System	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:45:56
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User entered 'mmHg'	System	10 Sep 2020 14:39:13

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47

**US3612031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47

**US3612031**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:31
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:39:21
	(b) (4)	

**US3612031**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:31
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 14:39:21
	(b) (4)	

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:00:48**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered (b) (6) club meetings with other members frequently.'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

**US3612031**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:00:48**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered '0'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered 'I'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:40:36

US3612031

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 14:40:36

**US3612031**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:47
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:47:39
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:40:36
	(b) (4)	

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:47:51
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:51

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:47:51
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 14:40:51

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:47:51
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	10 Sep 2020 14:40:51

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'VISIT1'	System	10 Sep 2020 14:40:51

US3612031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:01
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:46

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:48**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:01
User entered '190300'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 14:34:46

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:01
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:48

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:01
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:41:38

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:01
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:41:38

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:48**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:01
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:41:38

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Randomization**

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:01
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 14:41:38

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:01
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:41:38

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Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:16:13
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 03:35:27
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'Updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	09 Dec 2020 18:51:17
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	09 Dec 2020 18:51:05
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 21:31:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:09:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:57:39

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Pre-Dose (PREDOSE)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '09:04'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '10 Sep 2020 09:04'	System	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '98.2' F	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered 'Oral (Oral)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered empty.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per source, HR is 82. Please review and update source and/or EDC as needed. ' (Site from CRA).	(b) (4)	30 Sep 2020 15:35:19
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:35:17
Query 'Per source, HR is 82. Please review and update source and/or EDC as needed. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 22:04:06
User entered '82' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 22:04:01
User opened query 'Per source, HR is 82. Please review and update source and/or EDC as needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 16:46:41
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '68'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'bpm'	System	10 Sep 2020 14:42:23

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:46:20
User entered '21'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'breaths/min'	System	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '144'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '88'	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered missing code ND - Not Done.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Post-Dose (POSTDOSE)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:46:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 20:54:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 20:54:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 14:42:23
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:46:20
User entered '10 Sep 2020' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '11:22' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '10 Sep 2020 11:22'	System	10 Sep 2020 20:54:12
User entered empty.	System	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '98.2' F reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:46:20
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '74' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'bpm'	System	10 Sep 2020 20:54:12
User entered empty.	System	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '20' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4) Amy McMahan (b) (4) (b) (4)	10 Sep 2020 14:42:23

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'breaths/min'	System	10 Sep 2020 20:54:12
User entered empty.	System	10 Sep 2020 14:42:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '130' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	10 Sep 2020 20:54:12
User entered empty.	System	10 Sep 2020 14:42:23

US3612031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:46:20
User entered '82' reason for change: Data Entry Error	Amy McMahan (b) (4)	10 Sep 2020 20:54:12
User entered empty.	(b) (4)	
	Amy McMahan (b) (4)	10 Sep 2020 14:42:23
	(b) (4)	

US3612031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	10 Sep 2020 20:54:12
User entered empty.	System	10 Sep 2020 14:42:23

US3612031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per CRF guidelines, if screening and VID1 are completed on same day PE is to be documented in the screening visit.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:35:04
Query 'Per CRF guidelines, if screening and VID1 are completed on same day PE is to be documented in the screening visit.' answered with 'Updated' (Site from CRA). DataPoint Un-verified.	Amy McMahan (b) (4)	28 Sep 2020 22:03:33
User entered 'No (N)' reason for change: Data Entry Error	Amy McMahan (b) (4)	28 Sep 2020 22:03:29
User opened query 'Per CRF guidelines, if screening and VID1 are completed on same day PE is to be documented in the screening visit.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:48:42
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:43:11

US3612031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	30 Sep 2020 15:35:06
DataPoint Un-verified.	Amy McMahan (b) (4)	28 Sep 2020 22:03:29
User entered empty; reason for change Data Entry Error	Amy McMahan (b) (4)	28 Sep 2020 22:03:29
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:48:10
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 14:43:11

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:52
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 15:59:31

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:52
User entered empty.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:59:31

US3612031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:48:52
User entered empty.	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:59:31

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:59:31

US3612031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:52
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 15:59:31

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:48:52
User entered '10:49'	Amy McMahan (b) (4)	10 Sep 2020 15:59:31

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '10 Sep 2020 10:49'	System	10 Sep 2020 15:59:31

US3612031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
User closed query 'Per source, injection was given in LEFT deltoid. please review source and EDC and update as needed. ' (Site from CRA).	(b) (4)	30 Sep 2020 15:34:23
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 15:34:21
Query 'Per source, injection was given in LEFT deltoid. please review source and EDC and update as needed. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 22:01:37
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 22:01:32
User opened query 'Per source, injection was given in LEFT deltoid. please review source and EDC and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:49:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 16:49:00
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:48:52
User entered 'Right Arm (RIGHT ARM)'	Amy McMahan (b) (4)	10 Sep 2020 15:59:31

US3612031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:48:52
User entered 'ONCE'	System	10 Sep 2020 15:59:31

US3612031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:41
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:45

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:41
User entered '10 Sep 2020'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:45

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:41
User entered '09:50'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:45

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '10 Sep 2020 09:50'	System	10 Sep 2020 15:07:45

US3612031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:00:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:49:46
User entered '10 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:46
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:46
User entered '09:56'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '10 Sep 2020 09:56'	System	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:49:46
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 15:07:58
	(b) (4)	

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:49:46
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered empty.	System	10 Sep 2020 15:07:58

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	23 Sep 2020 16:49:53
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 14:43:26

**US3612031**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'I'	System	10 Sep 2020 14:43:26

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e985c9f-ac6a-4ae8-b906-28538934bd36' User entered 'Yes (Y)'	System	10 Sep 2020 16:19:42
	System	10 Sep 2020 16:19:42

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:26', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e985c9f-ac6a-4ae8-b906-28538934bd36' User entered '98.2'	System	10 Sep 2020 16:19:42
	System	10 Sep 2020 16:19:42

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:33', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e985c9f-ac6a-4ae8-b906-28538934bd36'	System	10 Sep 2020 16:19:42
User entered 'No (N)'	System	10 Sep 2020 16:19:42

**US3612031**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e985c9f-ac6a-4ae8-b906-28538934bd36' User entered '10 Sep 2020 11:19'	System	10 Sep 2020 16:19:42
	System	10 Sep 2020 16:19:42

**US3612031**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 11:09'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 13:39'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:33:52', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b0a031d6-3481-4554-b493-c6bae3d8d6d4' User entered 'Yes (Y)'	System	11 Sep 2020 01:34:10
	System	11 Sep 2020 01:34:10

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:33:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b0a031d6-3481-4554-b493-c6bae3d8d6d4' User entered '97.6'	System	11 Sep 2020 01:34:10
	System	11 Sep 2020 01:34:10

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b0a031d6-3481-4554-b493-c6bae3d8d6d4'	System	11 Sep 2020 01:34:10
User entered 'No (N)'	System	11 Sep 2020 01:34:10

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b0a031d6-3481-4554-b493-c6bae3d8d6d4'	System	11 Sep 2020 01:34:10
User entered '10 Sep 2020 20:34'	System	11 Sep 2020 01:34:10

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 14:34'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 2'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:21', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '1c096b17-0dee-45ee-a6a0-b3e80f754e5f' User entered 'Yes (Y)'	System	11 Sep 2020 17:01:12
	System	11 Sep 2020 17:01:12

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:31', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '1c096b17-0dee-45ee-a6a0-b3e80f754e5f' User entered '98.1'	System	11 Sep 2020 17:01:12
	System	11 Sep 2020 17:01:12

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '1c096b17-0dee-45ee-a6a0-b3e80f754e5f' User entered 'No (N)'	System	11 Sep 2020 17:01:12
	System	11 Sep 2020 17:01:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '1c096b17-0dee-45ee-a6a0-b3e80f754e5f' User entered '11 Sep 2020 12:00'	System	11 Sep 2020 17:01:12
	System	11 Sep 2020 17:01:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 3'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:50:23', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '4cfe394e-d8b7-4ee0-b3c4-2be69cf52386'	System	12 Sep 2020 17:52:50
User entered 'Yes (Y)'	System	12 Sep 2020 17:52:50

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:52:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '4cfe394e-d8b7-4ee0-b3c4-2be69cf52386' User entered '97.7'	System	12 Sep 2020 17:52:50
	System	12 Sep 2020 17:52:50

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:52:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '4cfe394e-d8b7-4ee0-b3c4-2be69cf52386'	System	12 Sep 2020 17:52:50
User entered 'No (N)'	System	12 Sep 2020 17:52:50

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:52:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '4cfe394e-d8b7-4ee0-b3c4-2be69cf52386'	System	12 Sep 2020 17:52:50
User entered '12 Sep 2020 12:52'	System	12 Sep 2020 17:52:50

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 4'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:13', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b4beea2b-46e6-42ba-bca8-e03285e1b634' User entered 'Yes (Y)'	System	13 Sep 2020 17:11:35
	System	13 Sep 2020 17:11:35

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b4beea2b-46e6-42ba-bca8-e03285e1b634' User entered '97.3'	System	13 Sep 2020 17:11:35
	System	13 Sep 2020 17:11:35

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:21', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b4beea2b-46e6-42ba-bca8-e03285e1b634' User entered 'No (N)'	System	13 Sep 2020 17:11:35
	System	13 Sep 2020 17:11:35

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b4beea2b-46e6-42ba-bca8-e03285e1b634' User entered '13 Sep 2020 12:11'	System	13 Sep 2020 17:11:35
	System	13 Sep 2020 17:11:35

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 5'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:16:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9abb08e6-f103-4c1c-8d5c-19a3aa21166d' User entered 'Yes (Y)'	System	15 Sep 2020 11:17:06
	System	15 Sep 2020 11:17:06

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:16:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9abb08e6-f103-4c1c-8d5c-19a3aa21166d' User entered '95.3'	System	15 Sep 2020 11:17:06
	System	15 Sep 2020 11:17:06

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:16:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9abb08e6-f103-4c1c-8d5c-19a3aa21166d' User entered 'No (N)'	System	15 Sep 2020 11:17:06
	System	15 Sep 2020 11:17:06

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:04', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9abb08e6-f103-4c1c-8d5c-19a3aa21166d' User entered '15 Sep 2020 06:17'	System	15 Sep 2020 11:17:06
	System	15 Sep 2020 11:17:06

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 6'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c3b247a0-809d-4fe4-afbd-49bc3af84be8' User entered 'Yes (Y)'	System	16 Sep 2020 00:03:25
	System	16 Sep 2020 00:03:25

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c3b247a0-809d-4fe4-afbd-49bc3af84be8' User entered '96.9'	System	16 Sep 2020 00:03:25
	System	16 Sep 2020 00:03:25

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:16', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c3b247a0-809d-4fe4-afbd-49bc3af84be8' User entered 'No (N)'	System	16 Sep 2020 00:03:25
	System	16 Sep 2020 00:03:25

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:20', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c3b247a0-809d-4fe4-afbd-49bc3af84be8' User entered '15 Sep 2020 19:03'	System	16 Sep 2020 00:03:25
	System	16 Sep 2020 00:03:25

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 7'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:04', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '32f28c6e-4898-4491-9e4f-d658e1f68560'	System	16 Sep 2020 17:32:18
User entered 'Yes (Y)'	System	16 Sep 2020 17:32:18

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '32f28c6e-4898-4491-9e4f-d658e1f68560' User entered '98.2'	System	16 Sep 2020 17:32:18
	System	16 Sep 2020 17:32:18

US3612031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '32f28c6e-4898-4491-9e4f-d658e1f68560'	System	16 Sep 2020 17:32:18
User entered 'No (N)'	System	16 Sep 2020 17:32:18

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:16', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '32f28c6e-4898-4491-9e4f-d658e1f68560' User entered '16 Sep 2020 12:32'	System	16 Sep 2020 17:32:18
	System	16 Sep 2020 17:32:18

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0ae93040-3a40-47f5-bc36-818dc7778535' User entered 'None (1)'	System	10 Sep 2020 16:20:28
	System	10 Sep 2020 16:20:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:19:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0ae93040-3a40-47f5-bc36-818dc7778535' User entered 'No (N)'	System	10 Sep 2020 16:20:28
	System	10 Sep 2020 16:20:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:20:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0ae93040-3a40-47f5-bc36-818dc7778535' User entered 'No (N)'	System	10 Sep 2020 16:20:28
	System	10 Sep 2020 16:20:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:20:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0ae93040-3a40-47f5-bc36-818dc7778535'	System	10 Sep 2020 16:20:28
User entered 'None (1)'	System	10 Sep 2020 16:20:28

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:20:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0ae93040-3a40-47f5-bc36-818dc7778535' User entered '10 Sep 2020 11:20'	System	10 Sep 2020 16:20:28
	System	10 Sep 2020 16:20:28

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 11:09'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 13:39'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f6502828-b0cb-4174-bfa3-0d620b195eef' User entered 'None (1)'	System	11 Sep 2020 01:34:28
	System	11 Sep 2020 01:34:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f6502828-b0cb-4174-bfa3-0d620b195eef' User entered 'No (N)'	System	11 Sep 2020 01:34:28
	System	11 Sep 2020 01:34:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f6502828-b0cb-4174-bfa3-0d620b195eef' User entered 'No (N)'	System	11 Sep 2020 01:34:28
	System	11 Sep 2020 01:34:28

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:20', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f6502828-b0cb-4174-bfa3-0d620b195eef' User entered 'None (1)'	System	11 Sep 2020 01:34:28
	System	11 Sep 2020 01:34:28

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:23', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f6502828-b0cb-4174-bfa3-0d620b195eef' User entered '10 Sep 2020 20:34'	System	11 Sep 2020 01:34:28
	System	11 Sep 2020 01:34:28

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 14:34'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 2'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b07f2d91-8ae7-4cf3-8ea0-0f01b856f0d4'	System	11 Sep 2020 17:01:54
User entered 'None (1)'	System	11 Sep 2020 17:01:54

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:00:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b07f2d91-8ae7-4cf3-8ea0-0f01b856f0d4' User entered 'No (N)'	System	11 Sep 2020 17:01:54
	System	11 Sep 2020 17:01:54

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:01', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b07f2d91-8ae7-4cf3-8ea0-0f01b856f0d4'	System	11 Sep 2020 17:01:54
User entered 'No (N)'	System	11 Sep 2020 17:01:54

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b07f2d91-8ae7-4cf3-8ea0-0f01b856f0d4'	System	11 Sep 2020 17:01:54
User entered 'None (1)'	System	11 Sep 2020 17:01:54

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b07f2d91-8ae7-4cf3-8ea0-0f01b856f0d4' User entered '11 Sep 2020 12:01'	System	11 Sep 2020 17:01:54
	System	11 Sep 2020 17:01:54

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 3'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:52:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '15f14549-9d6a-4695-ba46-d8b51aae3fc9' User entered 'None (1)'	System	12 Sep 2020 17:53:13
	System	12 Sep 2020 17:53:13

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '15f14549-9d6a-4695-ba46-d8b51aae3fc9' User entered 'No (N)'	System	12 Sep 2020 17:53:13
	System	12 Sep 2020 17:53:13

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '15f14549-9d6a-4695-ba46-d8b51aae3fc9' User entered 'No (N)'	System	12 Sep 2020 17:53:13
	System	12 Sep 2020 17:53:13

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:07', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '15f14549-9d6a-4695-ba46-d8b51aae3fc9' User entered 'None (1)'	System	12 Sep 2020 17:53:13
	System	12 Sep 2020 17:53:13

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '15f14549-9d6a-4695-ba46-d8b51aae3fc9' User entered '12 Sep 2020 12:53'	System	12 Sep 2020 17:53:13
	System	12 Sep 2020 17:53:13

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 4'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:37', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '47c74a1d-1ed8-4cf9-82a4-6db5839bd254' User entered 'None (1)'	System	13 Sep 2020 17:11:51
	System	13 Sep 2020 17:11:51

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:40', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '47c74a1d-1ed8-4cf9-82a4-6db5839bd254' User entered 'No (N)'	System	13 Sep 2020 17:11:51
	System	13 Sep 2020 17:11:51

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:43', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '47c74a1d-1ed8-4cf9-82a4-6db5839bd254' User entered 'No (N)'	System	13 Sep 2020 17:11:51
	System	13 Sep 2020 17:11:51

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:46', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '47c74a1d-1ed8-4cf9-82a4-6db5839bd254'	System	13 Sep 2020 17:11:51
User entered 'None (1)'	System	13 Sep 2020 17:11:51

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '47c74a1d-1ed8-4cf9-82a4-6db5839bd254' User entered '13 Sep 2020 12:11'	System	13 Sep 2020 17:11:51
	System	13 Sep 2020 17:11:51

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 5'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '61bbdd0f-d9be-49e3-885d-bc639d79d5bd' User entered 'None (1)'	System	15 Sep 2020 11:17:24
	System	15 Sep 2020 11:17:24

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '61bbdd0f-d9be-49e3-885d-bc639d79d5bd' User entered 'No (N)'	System	15 Sep 2020 11:17:24
	System	15 Sep 2020 11:17:24

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '61bbdd0f-d9be-49e3-885d-bc639d79d5bd' User entered 'No (N)'	System	15 Sep 2020 11:17:24
	System	15 Sep 2020 11:17:24

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '61bbdd0f-d9be-49e3-885d-bc639d79d5bd' User entered 'None (1)'	System	15 Sep 2020 11:17:24
	System	15 Sep 2020 11:17:24

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '61bbdd0f-d9be-49e3-885d-bc639d79d5bd' User entered '15 Sep 2020 06:17'	System	15 Sep 2020 11:17:24
	System	15 Sep 2020 11:17:24

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 6'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:30', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ad230ec-d042-4fc9-a868-fc1f050d8d35'	System	16 Sep 2020 00:03:47
User entered 'None (1)'	System	16 Sep 2020 00:03:47

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:34', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ad230ec-d042-4fc9-a868-fc1f050d8d35'	System	16 Sep 2020 00:03:47
User entered 'No (N)'	System	16 Sep 2020 00:03:47

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:37', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ad230ec-d042-4fc9-a868-fc1f050d8d35'	System	16 Sep 2020 00:03:47
User entered 'No (N)'	System	16 Sep 2020 00:03:47

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ad230ec-d042-4fc9-a868-fc1f050d8d35'	System	16 Sep 2020 00:03:47
User entered 'None (1)'	System	16 Sep 2020 00:03:47

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ad230ec-d042-4fc9-a868-fc1f050d8d35'	System	16 Sep 2020 00:03:47
User entered '15 Sep 2020 19:03'	System	16 Sep 2020 00:03:47

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 7'	System	10 Sep 2020 15:59:31

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:21', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3d549ef0-7e82-498a-beb2-12a219c6132b' User entered 'None (1)'	System	16 Sep 2020 17:32:45
	System	16 Sep 2020 17:32:45

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3d549ef0-7e82-498a-beb2-12a219c6132b' User entered 'No (N)'	System	16 Sep 2020 17:32:45
	System	16 Sep 2020 17:32:45

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3d549ef0-7e82-498a-beb2-12a219c6132b' User entered 'No (N)'	System	16 Sep 2020 17:32:45
	System	16 Sep 2020 17:32:45

US3612031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:37', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3d549ef0-7e82-498a-beb2-12a219c6132b' User entered 'None (1)'	System	16 Sep 2020 17:32:45
	System	16 Sep 2020 17:32:45

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3d549ef0-7e82-498a-beb2-12a219c6132b' User entered '16 Sep 2020 12:32'	System	16 Sep 2020 17:32:45
	System	16 Sep 2020 17:32:45

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:20:41', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19'	System	10 Sep 2020 16:22:06
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:25', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered 'None (0)'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:29', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered 'None (0)'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:33', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered 'None (0)'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered 'None (0)'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered 'None (0)'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:21:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19'	System	10 Sep 2020 16:22:06
User entered 'Yes (Y)'	System	10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T11:22:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bb275abb-11ec-4ccc-82bd-7ca33af66f19' User entered '10 Sep 2020 11:22'	System	10 Sep 2020 16:22:06
	System	10 Sep 2020 16:22:06

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 11:09'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 13:39'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:27', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:30', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:34', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered 'None (0)'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9'	System	11 Sep 2020 01:34:51
User entered 'No (N)'	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-10T20:34:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3a01dea9-0ebe-44f7-8877-9d5f79c464e9' User entered '10 Sep 2020 20:34'	System	11 Sep 2020 01:34:51
	System	11 Sep 2020 01:34:51

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Sep 2020 14:34'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 2'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:13', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:19', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:24', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'None (0)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:27', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered 'No (N)'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-11T12:01:30', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '5cde303b-812d-4d2c-a8a9-df143c278f34' User entered '11 Sep 2020 12:01'	System	11 Sep 2020 17:02:18
	System	11 Sep 2020 17:02:18

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 3'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:20', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:25', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:27', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'None (0)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered 'No (N)'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-12T12:53:35', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '43123f7a-dd76-4b56-9fec-a7ecaba158b6' User entered '12 Sep 2020 12:53'	System	12 Sep 2020 17:53:39
	System	12 Sep 2020 17:53:39

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 4'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:11:57', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:12:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:12:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:12:04', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'None (0)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:12:07', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered 'No (N)'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-13T12:12:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '69401d75-bad9-4848-9ac5-5ec2921b9e9a' User entered '13 Sep 2020 12:12'	System	13 Sep 2020 17:12:15
	System	13 Sep 2020 17:12:15

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 5'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:26', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:31', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:34', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered 'None (0)'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695'	System	15 Sep 2020 11:17:51
User entered 'No (N)'	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T06:17:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7a4f23b9-b992-4159-9f37-a7927c14e695' User entered '15 Sep 2020 06:17'	System	15 Sep 2020 11:17:51
	System	15 Sep 2020 11:17:51

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 6'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5' User entered 'None (0)'	System	16 Sep 2020 00:04:21
	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:03:57', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5'	System	16 Sep 2020 00:04:21
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5'	System	16 Sep 2020 00:04:21
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5'	System	16 Sep 2020 00:04:21
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5' User entered 'None (0)'	System	16 Sep 2020 00:04:21
	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5' User entered 'None (0)'	System	16 Sep 2020 00:04:21
	System	16 Sep 2020 00:04:21

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:14', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5' User entered 'No (N)'	System	16 Sep 2020 00:04:21
	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-15T19:04:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3e14baa5-1f3b-4fca-a298-25638d4837a5' User entered '15 Sep 2020 19:04'	System	16 Sep 2020 00:04:21
	System	16 Sep 2020 00:04:21

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 7'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:32:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:33:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:33:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'None (0)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

US3612031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:33:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered 'No (N)'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-09-16T12:33:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '083d7939-73ec-48bf-9819-2ac931db6571' User entered '16 Sep 2020 12:33'	System	16 Sep 2020 17:33:12
	System	16 Sep 2020 17:33:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:59:31

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:36:10
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Sep 2020 21:40:31

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:36:10
User entered '17 Sep 2020'	Amy McMahan (b) (4)	17 Sep 2020 21:40:31

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:36:10
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4)	17 Sep 2020 21:40:31

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:36:10
User entered empty.	Amy McMahan (b) (4)	17 Sep 2020 21:40:31

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:36:13
User entered 'Yes (Y)'	Amy McMahan (b) (4)	17 Sep 2020 21:40:36

**US3612031**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	17 Sep 2020 21:40:36

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:29:40
User entered 'Yes (Y)'	Amy McMahan (b) (4)	28 Sep 2020 13:23:56

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:29:40
User entered '25 Sep 2020'	Amy McMahan (b) (4) (b) (4)	28 Sep 2020 13:23:56

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:29:40
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4)	28 Sep 2020 13:23:56

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:29:40
User entered empty.	Amy McMahan (b) (4)	28 Sep 2020 13:23:56

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	07 Oct 2020 16:29:35
User entered 'Yes (Y)'	Amy McMahan (b) (4)	28 Sep 2020 13:24:02

**US3612031**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	28 Sep 2020 13:24:02

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:31:09
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Oct 2020 22:41:51

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:31:09
User entered '1 Oct 2020'	Amy McMahan (b) (4)	01 Oct 2020 22:41:51

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:31:09
User entered 'Contact Made (CONTACT MADE)'	Amy McMahan (b) (4) (b) (4)	01 Oct 2020 22:41:51

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:31:09
User entered empty.	Amy McMahan (b) (4) (b) (4)	01 Oct 2020 22:41:51

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:31:18
User entered 'Yes (Y)'	Amy McMahan (b) (4)	01 Oct 2020 22:41:42

**US3612031**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	01 Oct 2020 22:41:42

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:39:13
User entered 'Yes (Y)'	Amy McMahan (b) (4)	06 Oct 2020 18:24:22

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:39:13
User entered '6 Oct 2020'	Amy McMahan (b) (4)	06 Oct 2020 18:24:22

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:39:13
User entered 'Clinic (Clinic)'	Amy McMahan (b) (4)	06 Oct 2020 18:24:22

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'VISIT2'	System	06 Oct 2020 18:24:22

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered 'Yes (Y)'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '06 Oct 2020'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '12:00' reason for change: Data Entry Error	Amber Stanford (b) (4)	07 Oct 2020 14:06:12
User entered '12:15'	(b) (4) Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '06 Oct 2020 12:00'	System	07 Oct 2020 14:06:12
User entered '06 Oct 2020 12:15'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '098.2' F	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered empty.	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '89'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'bpm'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '18'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'breaths/min'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '141'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '91'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered 'Yes (Y)'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '06 Oct 2020'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '13:18' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:05:18
User entered '12:21'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '06 Oct 2020 13:18'	System	07 Oct 2020 14:05:18
User entered '06 Oct 2020 12:21'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '098.1' F	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:41:13
	(b) (4)	
	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '85'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'bpm'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:41:13
User entered '18'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'breaths/min'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '142'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	07 Oct 2020 14:03:32

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 20:41:13
User entered '96'	Amber Stanford (b) (4)	07 Oct 2020 14:03:32
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	07 Oct 2020 14:03:32

US3612031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:00
User entered 'Yes (Y)'	Amy McMahan (b) (4)	06 Oct 2020 18:24:30

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:00
User entered '6 Oct 2020'	Amy McMahan (b) (4)	06 Oct 2020 18:24:30

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:07
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 18:24:12

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:07
User entered empty.	Amy McMahan (b) (4)	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:07
User entered empty.	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 18:24:12

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:07
User entered '6 Oct 2020'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:07
User entered '12:41'	Amy McMahan (b) (4) (b) (4)	06 Oct 2020 18:24:12

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '6 Oct 2020 12:41'	System	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:07
User entered 'Left Arm (LEFT ARM)'	Amy McMahan (b) (4)	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 20:42:07
User entered 'ONCE'	System	06 Oct 2020 18:24:12

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 18:24:12

US3612031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:44
User entered 'Yes (Y)'	Amber Stanford (b) (4)	07 Oct 2020 14:04:46

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:44
User entered '06 Oct 2020'	Amber Stanford (b) (4)	07 Oct 2020 14:04:46

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:44
User entered '12:15' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:06:39
User entered '12:21'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:04:46

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '06 Oct 2020 12:15'	System	07 Oct 2020 14:06:39
User entered '06 Oct 2020 12:21'	System	07 Oct 2020 14:04:46

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:49
User entered '06 Oct 2020'	Amber Stanford (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:49
User entered 'Yes (Y)'	Amber Stanford (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:42:49
User entered '12:21'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '06 Oct 2020 12:21'	System	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Stanford (b) (4) (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:49
User entered 'No (N)'	Amber Stanford (b) (4)	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:49
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 20:42:49
	(b) (4)	
	Amber Stanford (b) (4)	07 Oct 2020 14:06:58
	(b) (4)	

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered empty.	System	07 Oct 2020 14:06:58

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:42:57
User entered 'Yes (Y)'	Amy McMahan (b) (4)	06 Oct 2020 18:24:35

**US3612031**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'I'	System	06 Oct 2020 18:24:35

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd61d3621-01d3-471c-bda9-1e52369006d5' User entered 'Yes (Y)'	System	06 Oct 2020 18:26:48
	System	06 Oct 2020 18:26:48

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd61d3621-01d3-471c-bda9-1e52369006d5' User entered '98.1'	System	06 Oct 2020 18:26:48
	System	06 Oct 2020 18:26:48

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:41', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd61d3621-01d3-471c-bda9-1e52369006d5'	System	06 Oct 2020 18:26:48
User entered 'No (N)'	System	06 Oct 2020 18:26:48

**US3612031**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd61d3621-01d3-471c-bda9-1e52369006d5' User entered '06 Oct 2020 13:26'	System	06 Oct 2020 18:26:48
	System	06 Oct 2020 18:26:48

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 13:01'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 15:31'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:30:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '678db36a-7a4b-467a-bddb-72f3da44c409'	System	07 Oct 2020 03:31:13
User entered 'Yes (Y)'	System	07 Oct 2020 03:31:13

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '678db36a-7a4b-467a-bddb-72f3da44c409' User entered '95.2'	System	07 Oct 2020 03:31:13
	System	07 Oct 2020 03:31:13

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:04', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '678db36a-7a4b-467a-bddb-72f3da44c409'	System	07 Oct 2020 03:31:13
User entered 'No (N)'	System	07 Oct 2020 03:31:13

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '678db36a-7a4b-467a-bddb-72f3da44c409' User entered '06 Oct 2020 22:31'	System	07 Oct 2020 03:31:13
	System	07 Oct 2020 03:31:13

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 16:26'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 2'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '86549c57-9eac-4cc5-9425-1c0aa700791b' User entered 'Yes (Y)'	System	07 Oct 2020 17:09:25
	System	07 Oct 2020 17:09:25

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:16', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '86549c57-9eac-4cc5-9425-1c0aa700791b' User entered '96.8'	System	07 Oct 2020 17:09:25
	System	07 Oct 2020 17:09:25

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:20', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '86549c57-9eac-4cc5-9425-1c0aa700791b' User entered 'No (N)'	System	07 Oct 2020 17:09:25
	System	07 Oct 2020 17:09:25

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:23', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '86549c57-9eac-4cc5-9425-1c0aa700791b' User entered '07 Oct 2020 12:09'	System	07 Oct 2020 17:09:25
	System	07 Oct 2020 17:09:25

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 3'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '81a4a686-8a5d-44f0-b511-f5665ad09b2b' User entered 'Yes (Y)'	System	08 Oct 2020 17:24:30
	System	08 Oct 2020 17:24:30

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:13', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '81a4a686-8a5d-44f0-b511-f5665ad09b2b' User entered '96.3'	System	08 Oct 2020 17:24:30
	System	08 Oct 2020 17:24:30

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:16', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '81a4a686-8a5d-44f0-b511-f5665ad09b2b' User entered 'No (N)'	System	08 Oct 2020 17:24:30
	System	08 Oct 2020 17:24:30

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '81a4a686-8a5d-44f0-b511-f5665ad09b2b' User entered '08 Oct 2020 12:24'	System	08 Oct 2020 17:24:30
	System	08 Oct 2020 17:24:30

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 4'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b73c8e64-7a40-4db9-84d8-8fa41e0329c9'	System	09 Oct 2020 18:47:25
User entered 'Yes (Y)'	System	09 Oct 2020 18:47:25

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b73c8e64-7a40-4db9-84d8-8fa41e0329c9' User entered '98.0'	System	09 Oct 2020 18:47:25
	System	09 Oct 2020 18:47:25

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:20', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b73c8e64-7a40-4db9-84d8-8fa41e0329c9'	System	09 Oct 2020 18:47:25
User entered 'No (N)'	System	09 Oct 2020 18:47:25

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:24', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b73c8e64-7a40-4db9-84d8-8fa41e0329c9' User entered '09 Oct 2020 13:47'	System	09 Oct 2020 18:47:25
	System	09 Oct 2020 18:47:25

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 5'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:29', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '11c219d8-47a1-49b9-998b-b36ff1e8baa9' User entered 'Yes (Y)'	System	10 Oct 2020 17:54:42
	System	10 Oct 2020 17:54:42

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:33', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '11c219d8-47a1-49b9-998b-b36ff1e8baa9' User entered '97.4'	System	10 Oct 2020 17:54:42
	System	10 Oct 2020 17:54:42

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '11c219d8-47a1-49b9-998b-b36ff1e8baa9' User entered 'No (N)'	System	10 Oct 2020 17:54:42
	System	10 Oct 2020 17:54:42

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '11c219d8-47a1-49b9-998b-b36ff1e8baa9' User entered '10 Oct 2020 12:54'	System	10 Oct 2020 17:54:42
	System	10 Oct 2020 17:54:42

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 6'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '24b7d5fe-0341-4cc1-8f9b-04ad564d909d' User entered 'Yes (Y)'	System	11 Oct 2020 21:20:37
	System	11 Oct 2020 21:20:37

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:26', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '24b7d5fe-0341-4cc1-8f9b-04ad564d909d' User entered '97.7'	System	11 Oct 2020 21:20:37
	System	11 Oct 2020 21:20:37

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:29', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '24b7d5fe-0341-4cc1-8f9b-04ad564d909d' User entered 'No (N)'	System	11 Oct 2020 21:20:37
	System	11 Oct 2020 21:20:37

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:34', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '24b7d5fe-0341-4cc1-8f9b-04ad564d909d' User entered '11 Oct 2020 16:20'	System	11 Oct 2020 21:20:37
	System	11 Oct 2020 21:20:37

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 7'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:22', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f174d2a5-bbc4-40f8-a7bb-fdec905d0f95' User entered 'Yes (Y)'	System	12 Oct 2020 17:02:52
	System	12 Oct 2020 17:02:52

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:26', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f174d2a5-bbc4-40f8-a7bb-fdec905d0f95' User entered '98.2'	System	12 Oct 2020 17:02:52
	System	12 Oct 2020 17:02:52

US3612031

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:30', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f174d2a5-bbc4-40f8-a7bb-fdec905d0f95' User entered 'No (N)'	System	12 Oct 2020 17:02:52
	System	12 Oct 2020 17:02:52

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:35', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'f174d2a5-bbc4-40f8-a7bb-fdec905d0f95' User entered '12 Oct 2020 12:02'	System	12 Oct 2020 17:02:52
	System	12 Oct 2020 17:02:52

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a932bc15-103e-4a01-a795-7b12025176a1' User entered 'None (1)'	System	06 Oct 2020 18:27:06
	System	06 Oct 2020 18:27:06

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a932bc15-103e-4a01-a795-7b12025176a1' User entered 'No (N)'	System	06 Oct 2020 18:27:06
	System	06 Oct 2020 18:27:06

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:56', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a932bc15-103e-4a01-a795-7b12025176a1' User entered 'No (N)'	System	06 Oct 2020 18:27:06
	System	06 Oct 2020 18:27:06

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:26:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a932bc15-103e-4a01-a795-7b12025176a1' User entered 'None (1)'	System	06 Oct 2020 18:27:06
	System	06 Oct 2020 18:27:06

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a932bc15-103e-4a01-a795-7b12025176a1' User entered '06 Oct 2020 13:27'	System	06 Oct 2020 18:27:06
	System	06 Oct 2020 18:27:06

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 13:01'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 15:31'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '173e602d-108e-4a61-a09c-553d7cc670d9' User entered 'None (1)'	System	07 Oct 2020 03:31:54
	System	07 Oct 2020 03:31:54

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '173e602d-108e-4a61-a09c-553d7cc670d9' User entered 'No (N)'	System	07 Oct 2020 03:31:54
	System	07 Oct 2020 03:31:54

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '173e602d-108e-4a61-a09c-553d7cc670d9' User entered 'No (N)'	System	07 Oct 2020 03:31:54
	System	07 Oct 2020 03:31:54

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '173e602d-108e-4a61-a09c-553d7cc670d9' User entered 'None (1)'	System	07 Oct 2020 03:31:54
	System	07 Oct 2020 03:31:54

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '173e602d-108e-4a61-a09c-553d7cc670d9' User entered '06 Oct 2020 22:31'	System	07 Oct 2020 03:31:54
	System	07 Oct 2020 03:31:54

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 16:26'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 2'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:40', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '06cb24ac-073c-4e70-bb16-043c35aeb6b3' User entered 'None (1)'	System	07 Oct 2020 17:09:58
	System	07 Oct 2020 17:09:58

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '06cb24ac-073c-4e70-bb16-043c35aeb6b3' User entered 'No (N)'	System	07 Oct 2020 17:09:58
	System	07 Oct 2020 17:09:58

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '06cb24ac-073c-4e70-bb16-043c35aeb6b3' User entered 'No (N)'	System	07 Oct 2020 17:09:58
	System	07 Oct 2020 17:09:58

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:54', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '06cb24ac-073c-4e70-bb16-043c35aeb6b3' User entered 'None (1)'	System	07 Oct 2020 17:09:58
	System	07 Oct 2020 17:09:58

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:09:56', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '06cb24ac-073c-4e70-bb16-043c35aeb6b3' User entered '07 Oct 2020 12:09'	System	07 Oct 2020 17:09:58
	System	07 Oct 2020 17:09:58

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 3'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:33', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1709228-557e-426d-8f5b-ed0c4659e75e' User entered 'None (1)'	System	08 Oct 2020 17:24:48
	System	08 Oct 2020 17:24:48

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:37', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1709228-557e-426d-8f5b-ed0c4659e75e' User entered 'No (N)'	System	08 Oct 2020 17:24:48
	System	08 Oct 2020 17:24:48

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:40', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1709228-557e-426d-8f5b-ed0c4659e75e' User entered 'No (N)'	System	08 Oct 2020 17:24:48
	System	08 Oct 2020 17:24:48

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1709228-557e-426d-8f5b-ed0c4659e75e' User entered 'None (1)'	System	08 Oct 2020 17:24:48
	System	08 Oct 2020 17:24:48

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1709228-557e-426d-8f5b-ed0c4659e75e' User entered '08 Oct 2020 12:24'	System	08 Oct 2020 17:24:48
	System	08 Oct 2020 17:24:48

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 4'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '658cd213-d448-4057-86c3-b35ef56acd5b' User entered 'None (1)'	System	09 Oct 2020 18:47:41
	System	09 Oct 2020 18:47:41

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:30', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '658cd213-d448-4057-86c3-b35ef56acd5b' User entered 'No (N)'	System	09 Oct 2020 18:47:41
	System	09 Oct 2020 18:47:41

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:34', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '658cd213-d448-4057-86c3-b35ef56acd5b' User entered 'No (N)'	System	09 Oct 2020 18:47:41
	System	09 Oct 2020 18:47:41

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '658cd213-d448-4057-86c3-b35ef56acd5b' User entered 'None (1)'	System	09 Oct 2020 18:47:41
	System	09 Oct 2020 18:47:41

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:40', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '658cd213-d448-4057-86c3-b35ef56acd5b' User entered '09 Oct 2020 13:47'	System	09 Oct 2020 18:47:41
	System	09 Oct 2020 18:47:41

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 5'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:43', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0e0c4591-2767-4bc5-b441-f7e0a13afd6a' User entered 'None (1)'	System	10 Oct 2020 17:54:55
	System	10 Oct 2020 17:54:55

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:46', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0e0c4591-2767-4bc5-b441-f7e0a13afd6a' User entered 'No (N)'	System	10 Oct 2020 17:54:55
	System	10 Oct 2020 17:54:55

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0e0c4591-2767-4bc5-b441-f7e0a13afd6a' User entered 'No (N)'	System	10 Oct 2020 17:54:55
	System	10 Oct 2020 17:54:55

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:52', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0e0c4591-2767-4bc5-b441-f7e0a13afd6a' User entered 'None (1)'	System	10 Oct 2020 17:54:55
	System	10 Oct 2020 17:54:55

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:54', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0e0c4591-2767-4bc5-b441-f7e0a13afd6a' User entered '10 Oct 2020 12:54'	System	10 Oct 2020 17:54:55
	System	10 Oct 2020 17:54:55

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 6'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:41', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd3db31e4-5d49-407e-b2b4-997db39c5faf' User entered 'None (1)'	System	11 Oct 2020 21:20:56
	System	11 Oct 2020 21:20:56

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd3db31e4-5d49-407e-b2b4-997db39c5faf' User entered 'No (N)'	System	11 Oct 2020 21:20:56
	System	11 Oct 2020 21:20:56

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd3db31e4-5d49-407e-b2b4-997db39c5faf' User entered 'No (N)'	System	11 Oct 2020 21:20:56
	System	11 Oct 2020 21:20:56

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:51', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd3db31e4-5d49-407e-b2b4-997db39c5faf' User entered 'None (1)'	System	11 Oct 2020 21:20:56
	System	11 Oct 2020 21:20:56

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:54', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd3db31e4-5d49-407e-b2b4-997db39c5faf' User entered '11 Oct 2020 16:20'	System	11 Oct 2020 21:20:56
	System	11 Oct 2020 21:20:56

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 7'	System	06 Oct 2020 18:24:12

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ef7f134f-a8e4-4f03-ac1d-3f8b6ba035f4'	System	12 Oct 2020 17:02:59
User entered 'None (1)'	System	12 Oct 2020 17:02:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ef7f134f-a8e4-4f03-ac1d-3f8b6ba035f4' User entered 'No (N)'	System	12 Oct 2020 17:02:59
	System	12 Oct 2020 17:02:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ef7f134f-a8e4-4f03-ac1d-3f8b6ba035f4' User entered 'No (N)'	System	12 Oct 2020 17:02:59
	System	12 Oct 2020 17:02:59

US3612031

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:47', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ef7f134f-a8e4-4f03-ac1d-3f8b6ba035f4'	System	12 Oct 2020 17:02:59
User entered 'None (1)'	System	12 Oct 2020 17:02:59

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:51', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ef7f134f-a8e4-4f03-ac1d-3f8b6ba035f4'	System	12 Oct 2020 17:02:59
User entered '12 Oct 2020 12:02'	System	12 Oct 2020 17:02:59

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:07', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:14', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:19', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'None (0)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:25', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered 'No (N)'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T13:27:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c48bf6d0-8c35-48e5-a2d7-349ecc54613f' User entered '06 Oct 2020 13:27'	System	06 Oct 2020 18:27:32
	System	06 Oct 2020 18:27:32

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 13:01'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 15:31'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:31:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:01', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:04', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:13', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'None (0)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:17', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered 'No (N)'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-06T22:32:21', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd353d231-47f8-4136-ab40-20d0b0670529' User entered '06 Oct 2020 22:32'	System	07 Oct 2020 03:32:23
	System	07 Oct 2020 03:32:23

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '06 Oct 2020 16:26'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 2'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'None (0)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered 'No (N)'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-07T12:10:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ed2fe498-3641-4dc9-ac61-f79a3183b058' User entered '07 Oct 2020 12:10'	System	07 Oct 2020 17:10:22
	System	07 Oct 2020 17:10:22

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 3'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:49', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:51', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:56', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:24:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:25:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'None (0)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:25:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered 'No (N)'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-08T12:25:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e171df24-9665-404e-ac10-e68450860beb' User entered '08 Oct 2020 12:25'	System	08 Oct 2020 17:25:08
	System	08 Oct 2020 17:25:08

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

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

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 4'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:43', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:46', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:52', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered 'None (0)'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:47:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac'	System	09 Oct 2020 18:48:05
User entered 'No (N)'	System	09 Oct 2020 18:48:05

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-09T13:48:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c4df335f-3b37-44e5-b2fa-b0772894beac' User entered '09 Oct 2020 13:48'	System	09 Oct 2020 18:48:05
	System	09 Oct 2020 18:48:05

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 5'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:54:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:07', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'None (0)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered 'No (N)'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-10T12:55:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'bc2b5906-4b84-4551-8b99-17fe33e576ad' User entered '10 Oct 2020 12:55'	System	10 Oct 2020 17:55:17
	System	10 Oct 2020 17:55:17

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 6'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:20:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:09', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered 'None (0)'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:14', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9'	System	11 Oct 2020 21:21:22
User entered 'No (N)'	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-11T16:21:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '9507cd2d-adc2-47dc-901f-27684b7de1d9' User entered '11 Oct 2020 16:21'	System	11 Oct 2020 21:21:22
	System	11 Oct 2020 21:21:22

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	06 Oct 2020 18:24:12
User entered 'Day 7'	System	06 Oct 2020 18:24:12

**US3612031**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:02:57', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:03', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered 'None (0)'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

US3612031

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:48

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)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:11', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b'	System	12 Oct 2020 17:03:19
User entered 'No (N)'	System	12 Oct 2020 17:03:19

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-10-12T12:03:14', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ccfdb4e7-e67c-4ff3-addb-7b4ff438c93b' User entered '12 Oct 2020 12:03'	System	12 Oct 2020 17:03:19
	System	12 Oct 2020 17:03:19

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:24:12

**US3612031**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:00:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:24:12

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:43:07
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 22:02:13

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:43:07
User entered '13 Oct 2020'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 22:02:13

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:43:07
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 22:02:13

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 20:43:07
User entered empty.	Amber Stanford (b) (4) (b) (4)	13 Oct 2020 22:02:13

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	20 Oct 2020 20:43:22
User entered 'Yes (Y)'	Amber Stanford (b) (4)	13 Oct 2020 22:02:17

**US3612031**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	13 Oct 2020 22:02:17

**US3612031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:06:50
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:15:48

**US3612031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:06:50
User entered '21 Oct 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:15:48

**US3612031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:06:50
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	02 Nov 2020 15:15:48

**US3612031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:06:50
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Nov 2020 15:15:48

US3612031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:07:00
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:15:52
	(b) (4)	

**US3612031**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	02 Nov 2020 15:15:52

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:07:14
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:16:09
	(b) (4)	

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:07:14
User entered '27 Oct 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:16:09

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:07:14
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	02 Nov 2020 15:16:09

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:07:14
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Nov 2020 15:16:09

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:07:19
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:16:15
	(b) (4)	

**US3612031**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:38
User entered 'I'	System	02 Nov 2020 15:16:15

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:07:55
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:16:27
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:07:55
User entered '02 Nov 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:16:27
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:07:55
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	02 Nov 2020 15:16:27

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'VISIT3'	System	02 Nov 2020 15:16:27

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '02 Nov 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '08:40'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '02 Nov 2020 08:40'	System	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '098.6' F	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:08:09
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered empty.	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '099'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'bpm'	System	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '020'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'breaths/min'	System	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '137'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:09
User entered '97'	Amber Stanford (b) (4)	02 Nov 2020 15:27:28
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'mmHg'	System	02 Nov 2020 15:27:28

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:24
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:27:44
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:08:24
User entered '02 Nov 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:27:44

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:45
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:28:03
	(b) (4)	

US3612031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:08:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under "Unscheduled" in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:01:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under "Unscheduled" in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' answered with 'Sponsor is aware. PPD lab had sites use unscheduled kits for visit three if correct kits were not shipped on time. ' (Site from DM).	Amy McMahan (b) (4) (b) (4)	13 Nov 2020 18:16:42
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02-Nov-2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under "Unscheduled" in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:07:34
User entered '02 Nov 2020'	Amber Stanford (b) (4) (b) (4)	02 Nov 2020 15:28:03

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:08:45
User entered '08:51'	Amber Stanford (b) (4)	02 Nov 2020 15:28:03
	(b) (4)	

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered '02 Nov 2020 08:51'	System	02 Nov 2020 15:28:03

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	18 Nov 2020 19:08:50
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:28:10

**US3612031**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'I'	System	02 Nov 2020 15:28:10

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 64'	System	10 Sep 2020 15:59:31

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:17:21
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'ROUTINE FOLLOW UP, NOT REPORTABLE. ' (Site from DM).	Amy McMahan (b) (4) (b) (4)	01 Dec 2020 20:26:57
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 17:23:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:03:12', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190'	System	12 Nov 2020 18:04:26
User entered 'Yes (Y)'	System	12 Nov 2020 18:04:26

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:03:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190'	System	12 Nov 2020 18:04:26
User entered 'No (N)'	System	12 Nov 2020 18:04:26

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:03:43', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190'	System	12 Nov 2020 18:04:26
User entered 'No (N)'	System	12 Nov 2020 18:04:26

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:03:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190'	System	12 Nov 2020 18:04:26
User entered 'Yes (Y)'	System	12 Nov 2020 18:04:26

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:03:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190'	System	12 Nov 2020 18:04:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 18:04:26

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-12T12:04:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '55e6f4cc-3b22-46da-8713-52faab190190' User entered '12 Nov 2020 12:04:05'	System	12 Nov 2020 18:04:26
	System	12 Nov 2020 18:04:26

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered 'Day 71'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-17T17:10:47', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1b78b98-16c7-4ede-b39d-212a4fcc8429'	System	17 Nov 2020 23:11:34
User entered 'Yes (Y)'	System	17 Nov 2020 23:11:34

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-17T17:11:07', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1b78b98-16c7-4ede-b39d-212a4fcc8429'	System	17 Nov 2020 23:11:34
User entered 'No (N)'	System	17 Nov 2020 23:11:34

US3612031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:48

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-17T17:11:14', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1b78b98-16c7-4ede-b39d-212a4fcc8429' User entered 'No (N)'	System	17 Nov 2020 23:11:34
	System	17 Nov 2020 23:11:34

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-17T17:11:24', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1b78b98-16c7-4ede-b39d-212a4fcc8429'	System	17 Nov 2020 23:11:34
User entered 'No (N)'	System	17 Nov 2020 23:11:34

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-17T17:11:31', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'd1b78b98-16c7-4ede-b39d-212a4fcc8429' User entered '17 Nov 2020 17:11:31'	System	17 Nov 2020 23:11:34
	System	17 Nov 2020 23:11:34

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:16:55
Data entry locked.	System	10 Sep 2020 15:59:31
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 15:59:31

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-21T11:50:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '39d5d263-5132-4eff-9831-ed2f9e2a04d4' User entered 'Yes (Y)'	System	21 Nov 2020 17:51:12
	System	21 Nov 2020 17:51:12

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-21T11:50:51', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '39d5d263-5132-4eff-9831-ed2f9e2a04d4'	System	21 Nov 2020 17:51:12
User entered 'No (N)'	System	21 Nov 2020 17:51:12

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-21T11:50:55', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '39d5d263-5132-4eff-9831-ed2f9e2a04d4' User entered 'No (N)'	System	21 Nov 2020 17:51:12
	System	21 Nov 2020 17:51:12

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-21T11:51:02', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '39d5d263-5132-4eff-9831-ed2f9e2a04d4'	System	21 Nov 2020 17:51:12
User entered 'No (N)'	System	21 Nov 2020 17:51:12

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-21T11:51:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '39d5d263-5132-4eff-9831-ed2f9e2a04d4' User entered '21 Nov 2020 11:51:08'	System	21 Nov 2020 17:51:12
	System	21 Nov 2020 17:51:12

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-28T13:08:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ef5fe6d-0588-4f05-98a9-dc39334ba018'	System	28 Nov 2020 19:08:36
User entered 'No (N)'	System	28 Nov 2020 19:08:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-28T13:08:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ef5fe6d-0588-4f05-98a9-dc39334ba018'	System	28 Nov 2020 19:08:36
User entered 'No (N)'	System	28 Nov 2020 19:08:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-11-28T13:08:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3ef5fe6d-0588-4f05-98a9-dc39334ba018' User entered '28 Nov 2020 13:08:32'	System	28 Nov 2020 19:08:36
	System	28 Nov 2020 19:08:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-08T19:59:06', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '714971b1-85b4-42a8-b9a6-1f58669dfa73' User entered 'No (N)'	System	09 Dec 2020 01:59:19
	System	09 Dec 2020 01:59:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-08T19:59:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '714971b1-85b4-42a8-b9a6-1f58669dfa73'	System	09 Dec 2020 01:59:19
User entered 'No (N)'	System	09 Dec 2020 01:59:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-08T19:59:15', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '714971b1-85b4-42a8-b9a6-1f58669dfa73' User entered '08 Dec 2020 19:59:15'	System	09 Dec 2020 01:59:19
	System	09 Dec 2020 01:59:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-16T20:20:56', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cad36bd-082f-4541-9289-eb23fbe3c80e' User entered 'No (N)'	System	17 Dec 2020 02:21:36
	System	17 Dec 2020 02:21:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-16T20:21:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cad36bd-082f-4541-9289-eb23fbe3c80e' User entered 'Yes (Y)'	System	17 Dec 2020 02:21:36
	System	17 Dec 2020 02:21:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Please 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-16T20:21:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cad36bd-082f-4541-9289-eb23fbe3c80e'	System	17 Dec 2020 02:21:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 02:21:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-16T20:21:24', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cad36bd-082f-4541-9289-eb23fbe3c80e' User entered '16 Dec 2020 20:21:24'	System	17 Dec 2020 02:21:36
	System	17 Dec 2020 02:21:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-19T16:49:53', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a6ac113c-57ca-4d16-a290-90d4e2e4f6bb' User entered 'No (N)'	System	19 Dec 2020 22:50:09
	System	19 Dec 2020 22:50:09

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-19T16:49:59', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a6ac113c-57ca-4d16-a290-90d4e2e4f6bb' User entered 'No (N)'	System	19 Dec 2020 22:50:09
	System	19 Dec 2020 22:50:09

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-19T16:50:05', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a6ac113c-57ca-4d16-a290-90d4e2e4f6bb' User entered '19 Dec 2020 16:50:05'	System	19 Dec 2020 22:50:09
	System	19 Dec 2020 22:50:09

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-26T08:32:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ca550720-76ac-47f0-90f8-a34783fa660b' User entered 'No (N)'	System	26 Dec 2020 14:33:07
	System	26 Dec 2020 14:33:07

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-26T08:32:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ca550720-76ac-47f0-90f8-a34783fa660b' User entered 'Yes (Y)'	System	26 Dec 2020 14:33:07
	System	26 Dec 2020 14:33:07

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Please 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-26T08:32:50', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ca550720-76ac-47f0-90f8-a34783fa660b'	System	26 Dec 2020 14:33:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 14:33:07

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2020-12-26T08:32:58', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'ca550720-76ac-47f0-90f8-a34783fa660b' User entered '26 Dec 2020 08:32:58'	System	26 Dec 2020 14:33:07
	System	26 Dec 2020 14:33:07

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-02T07:40:48', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cd2c9a0-d506-4b05-a5c7-291dfe6bf8cd' User entered 'No (N)'	System	02 Jan 2021 13:41:02

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-02T07:40:54', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cd2c9a0-d506-4b05-a5c7-291dfe6bf8cd' User entered 'No (N)'	System	02 Jan 2021 13:41:02

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-02T07:40:57', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '3cd2c9a0-d506-4b05-a5c7-291dfe6bf8cd' User entered '02 Jan 2021 07:40:57'	System	02 Jan 2021 13:41:02
	System	02 Jan 2021 13:41:02

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-13T04:23:32', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0db7551f-263b-465e-8e20-26ead73b897f' User entered 'No (N)'	System	13 Jan 2021 10:23:43
	System	13 Jan 2021 10:23:43

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-13T04:23:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0db7551f-263b-465e-8e20-26ead73b897f'	System	13 Jan 2021 10:23:43
User entered 'No (N)'	System	13 Jan 2021 10:23:43

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-13T04:23:40', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0db7551f-263b-465e-8e20-26ead73b897f' User entered '13 Jan 2021 04:23:40'	System	13 Jan 2021 10:23:43
	System	13 Jan 2021 10:23:43

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-16T10:38:21', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e5792a03-db13-4ae8-a01f-c482367bb85e' User entered 'No (N)'	System	16 Jan 2021 16:38:31
	System	16 Jan 2021 16:38:31

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-16T10:38:24', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e5792a03-db13-4ae8-a01f-c482367bb85e' User entered 'No (N)'	System	16 Jan 2021 16:38:31

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-16T10:38:28', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e5792a03-db13-4ae8-a01f-c482367bb85e' User entered '16 Jan 2021 10:38:28'	System	16 Jan 2021 16:38:31
	System	16 Jan 2021 16:38:31

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-25T15:03:26', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0a0f5350-17db-48c2-a65e-a3bd9465f035' User entered 'No (N)'	System	25 Jan 2021 21:03:36
	System	25 Jan 2021 21:03:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-25T15:03:29', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0a0f5350-17db-48c2-a65e-a3bd9465f035'	System	25 Jan 2021 21:03:36
User entered 'No (N)'	System	25 Jan 2021 21:03:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-25T15:03:33', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0a0f5350-17db-48c2-a65e-a3bd9465f035' User entered '25 Jan 2021 15:03:33'	System	25 Jan 2021 21:03:36
	System	25 Jan 2021 21:03:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-31T12:54:36', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0d1bb549-b146-4ad7-8a84-20669eed2529'	System	31 Jan 2021 18:54:45
User entered 'No (N)'	System	31 Jan 2021 18:54:45

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-31T12:54:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0d1bb549-b146-4ad7-8a84-20669eed2529' User entered 'No (N)'	System	31 Jan 2021 18:54:45

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-01-31T12:54:44', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '0d1bb549-b146-4ad7-8a84-20669eed2529' User entered '31 Jan 2021 12:54:44'	System	31 Jan 2021 18:54:45
	System	31 Jan 2021 18:54:45

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-08T18:10:08', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2fe8938c-10cd-4aa1-a429-d1514119ef82'	System	13 Feb 2021 21:46:11
User entered 'No (N)'	System	13 Feb 2021 21:46:11

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-08T18:10:13', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2fe8938c-10cd-4aa1-a429-d1514119ef82'	System	13 Feb 2021 21:46:11
User entered 'No (N)'	System	13 Feb 2021 21:46:11

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-08T18:10:18', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2fe8938c-10cd-4aa1-a429-d1514119ef82'	System	13 Feb 2021 21:46:11
User entered '08 Feb 2021 18:10:18'	System	13 Feb 2021 21:46:11

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-13T15:46:10', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2061decf-80e8-469e-8dfe-9013f4440426'	System	13 Feb 2021 21:46:54
User entered 'No (N)'	System	13 Feb 2021 21:46:54

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-13T15:46:46', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2061decf-80e8-469e-8dfe-9013f4440426'	System	13 Feb 2021 21:46:54
User entered 'No (N)'	System	13 Feb 2021 21:46:54

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-13T15:46:51', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '2061decf-80e8-469e-8dfe-9013f4440426' User entered '13 Feb 2021 15:46:51'	System	13 Feb 2021 21:46:54
	System	13 Feb 2021 21:46:54

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-22T13:43:39', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6b461193-47fb-4d5f-ba27-a7989e7537df' User entered 'No (N)'	System	22 Feb 2021 19:43:48

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-22T13:43:42', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6b461193-47fb-4d5f-ba27-a7989e7537df' User entered 'No (N)'	System	22 Feb 2021 19:43:48

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-02-22T13:43:45', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6b461193-47fb-4d5f-ba27-a7989e7537df' User entered '22 Feb 2021 13:43:45'	System	22 Feb 2021 19:43:48
	System	22 Feb 2021 19:43:48

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-01T12:02:25-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '75ea23ce-083f-46ef-8d93-e98f6c61ba33'	System	01 Mar 2021 18:10:00
User entered 'No (N)'	System	01 Mar 2021 18:10:00

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-01T12:02:28-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '75ea23ce-083f-46ef-8d93-e98f6c61ba33'	System	01 Mar 2021 18:10:00
User entered 'No (N)'	System	01 Mar 2021 18:10:00

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-01T12:02:33-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '75ea23ce-083f-46ef-8d93-e98f6c61ba33'	System	01 Mar 2021 18:10:00
User entered '01 Mar 2021 12:02:33'	System	01 Mar 2021 18:10:00

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-07T07:28:23-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '847c0b12-034c-42f9-8afb-bee1fca39694'	System	07 Mar 2021 13:28:36
User entered 'No (N)'	System	07 Mar 2021 13:28:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-07T07:28:29-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '847c0b12-034c-42f9-8afb-bee1fca39694'	System	07 Mar 2021 13:28:36
User entered 'No (N)'	System	07 Mar 2021 13:28:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-07T07:28:33-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '847c0b12-034c-42f9-8afb-bee1fca39694'	System	07 Mar 2021 13:28:36
User entered '07 Mar 2021 07:28:33'	System	07 Mar 2021 13:28:36

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-13T16:20:39-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '645d3e5d-3a95-44a8-96d0-4546072715d4'	System	13 Mar 2021 22:20:55
User entered 'No (N)'	System	13 Mar 2021 22:20:55

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-13T16:20:48-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '645d3e5d-3a95-44a8-96d0-4546072715d4'	System	13 Mar 2021 22:20:55
User entered 'No (N)'	System	13 Mar 2021 22:20:55

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-13T16:20:52-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '645d3e5d-3a95-44a8-96d0-4546072715d4'	System	13 Mar 2021 22:20:55
User entered '13 Mar 2021 16:20:52'	System	13 Mar 2021 22:20:55

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-23T12:25:08-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c9dd0822-4bc8-4e5e-b0b0-d60cbca80649'	System	23 Mar 2021 17:25:22
User entered 'No (N)'	System	23 Mar 2021 17:25:22

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-23T12:25:10-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c9dd0822-4bc8-4e5e-b0b0-d60cbca80649'	System	23 Mar 2021 17:25:22
User entered 'No (N)'	System	23 Mar 2021 17:25:22

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-23T12:25:20-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'c9dd0822-4bc8-4e5e-b0b0-d60cbca80649'	System	23 Mar 2021 17:25:22
User entered '23 Mar 2021 12:25:20'	System	23 Mar 2021 17:25:22

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-28T20:02:08-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e727780-dad5-46ff-980d-44a2915d3a24'	System	29 Mar 2021 01:08:13
User entered 'No (N)'	System	29 Mar 2021 01:08:13

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-28T20:02:13-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e727780-dad5-46ff-980d-44a2915d3a24'	System	29 Mar 2021 01:08:13
User entered 'No (N)'	System	29 Mar 2021 01:08:13

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-28T20:02:29-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '6e727780-dad5-46ff-980d-44a2915d3a24' User entered '28 Mar 2021 20:02:29'	System	29 Mar 2021 01:08:13
	System	29 Mar 2021 01:08:13

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-03T16:09:10-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b79bbdb5-92d9-4a16-876b-27600e3cb82b'	System	03 Apr 2021 21:09:19
User entered 'No (N)'	System	03 Apr 2021 21:09:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-03T16:09:13-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b79bbdb5-92d9-4a16-876b-27600e3cb82b'	System	03 Apr 2021 21:09:19
User entered 'No (N)'	System	03 Apr 2021 21:09:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-03T16:09:17-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'b79bbdb5-92d9-4a16-876b-27600e3cb82b'	System	03 Apr 2021 21:09:19
User entered '03 Apr 2021 16:09:17'	System	03 Apr 2021 21:09:19

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-11T18:17:27-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a332575c-2c6e-46eb-9514-9cdc01a9b509' User entered 'No (N)'	System	11 Apr 2021 23:17:38
	System	11 Apr 2021 23:17:38

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-11T18:17:30-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a332575c-2c6e-46eb-9514-9cdc01a9b509' User entered 'No (N)'	System	11 Apr 2021 23:17:38
	System	11 Apr 2021 23:17:38

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-11T18:17:34-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'a332575c-2c6e-46eb-9514-9cdc01a9b509'	System	11 Apr 2021 23:17:38
User entered '11 Apr 2021 18:17:34'	System	11 Apr 2021 23:17:38

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-18T19:44:09-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '45a24f33-1e72-4f85-b87a-040ba0f556d6'	System	19 Apr 2021 00:44:20
User entered 'No (N)'	System	19 Apr 2021 00:44:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-18T19:44:12-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '45a24f33-1e72-4f85-b87a-040ba0f556d6'	System	19 Apr 2021 00:44:20
User entered 'No (N)'	System	19 Apr 2021 00:44:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-18T19:44:16-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '45a24f33-1e72-4f85-b87a-040ba0f556d6'	System	19 Apr 2021 00:44:20
User entered '18 Apr 2021 19:44:16'	System	19 Apr 2021 00:44:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-27T10:22:49-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e8721b34-5d0d-448a-b068-fe3c0615cc05'	System	29 Apr 2021 03:12:29
User entered 'No (N)'	System	29 Apr 2021 03:12:29

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-27T10:22:51-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e8721b34-5d0d-448a-b068-fe3c0615cc05'	System	29 Apr 2021 03:12:29
User entered 'No (N)'	System	29 Apr 2021 03:12:29

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-04-27T10:22:54-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e8721b34-5d0d-448a-b068-fe3c0615cc05'	System	29 Apr 2021 03:12:29
User entered '27 Apr 2021 10:22:54'	System	29 Apr 2021 03:12:29

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-05-01T08:31:08-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e56efc64-f01b-4122-87b4-d6c2609c9e95'	System	01 May 2021 13:31:20
User entered 'No (N)'	System	01 May 2021 13:31:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

Have you been exposed to someone with 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 (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-05-01T08:31:15-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e56efc64-f01b-4122-87b4-d6c2609c9e95'	System	01 May 2021 13:31:20
User entered 'No (N)'	System	01 May 2021 13:31:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-05-01T08:31:18-05:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: 'e56efc64-f01b-4122-87b4-d6c2609c9e95'	System	01 May 2021 13:31:20
User entered '01 May 2021 08:31:18'	System	01 May 2021 13:31:20

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:02:25

**US3612031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:25
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:02:25

US3612031

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:00:48**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:24:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-01T12:02:40-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7b1d1719-c27c-458c-8525-e6732d798ef3'	System	01 Mar 2021 18:10:26
User entered 'No (N)'	System	01 Mar 2021 18:10:26

**US3612031**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:24:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7388AA75-D345-4EE9-9EBD-904BEB3D367F)', Time: '2021-03-01T12:02:45-06:00', User OID: 'PatientReportedOutcome (US3612031)', ODM File OID: '7b1d1719-c27c-458c-8525-e6732d798ef3'	System	01 Mar 2021 18:10:26
User entered '01 Mar 2021 12:02:45'	System	01 Mar 2021 18:10:26

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	06 Jan 2021 18:07:10
User entered 'Yes (Y)'	Amber Stanford (b) (4)	03 Dec 2020 23:11:12

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	06 Jan 2021 18:07:10
User entered '03 Dec 2020'	Amber Stanford (b) (4)	03 Dec 2020 23:11:12

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	06 Jan 2021 18:07:10
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4)	03 Dec 2020 23:11:12

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:07:10
User entered empty.	Amber Stanford (b) (4) (b) (4)	03 Dec 2020 23:11:12

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User signature succeeded.	Richard Rupp (b) (4)	05 Mar 2021 20:05:16
DataPoint Verified.	(b) (4)	06 Jan 2021 18:07:26
User entered 'Yes (Y)'	Amber Stanford (b) (4)	03 Dec 2020 23:11:18

**US3612031**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:46:49
User entered 'I'	System	03 Dec 2020 23:11:18

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:18:50
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	08 Jan 2021 21:56:19

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:18:50
User entered '07 Jan 2021'	Amber Stanford (b) (4) (b) (4)	08 Jan 2021 21:56:19

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:18:50
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	08 Jan 2021 21:56:19

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:18:50
User entered empty.	Amber Stanford (b) (4) (b) (4)	08 Jan 2021 21:56:19

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:18:22
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	08 Jan 2021 21:56:27

**US3612031**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User entered 'I'	System	08 Jan 2021 21:56:27

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:19:06
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	05 Feb 2021 22:58:31

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:19:06
User entered '3 Feb 2021'	Kristin Pollock (b) (4) (b) (4)	05 Feb 2021 22:58:31

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:19:06
User entered 'Contact Made (CONTACT MADE)'	Kristin Pollock (b) (4) (b) (4)	05 Feb 2021 22:58:31

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:19:06
User entered empty.	Kristin Pollock (b) (4) (b) (4)	05 Feb 2021 22:58:31

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:20:27
User entered 'Yes (Y)'	Kristin Pollock (b) (4) (b) (4)	05 Feb 2021 22:58:40

**US3612031**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User entered 'I'	System	05 Feb 2021 22:58:40

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:50:51
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	17 Mar 2021 15:30:19

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:50:51
User entered '05 Mar 2021'	Amber Stanford (b) (4) (b) (4)	17 Mar 2021 15:30:19

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:50:51
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	17 Mar 2021 15:30:19

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:50:51
User entered empty.	Amber Stanford (b) (4) (b) (4)	17 Mar 2021 15:30:19

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:51:02
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	17 Mar 2021 15:30:29

**US3612031**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:02:37
User entered 'I'	System	17 Mar 2021 15:30:29

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:03

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered '30 Mar 2021'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:03

US3612031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Clinic (Clinic)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:03

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 18:30:03

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

US3612031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:30:11

US3612031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:30:11

US3612031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:30:11

US3612031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:30:11

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:22

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:22

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:32

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered '30 Mar 2021'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:32

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
	(b) (4)	
User entered '09:18'	Amber Stanford (b) (4)	30 Mar 2021 18:30:32
	(b) (4)	

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:18'	System	30 Mar 2021 18:30:32

US3612031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:30:36

**US3612031**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:30:36

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:41
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:32:26
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 20:55:58

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:00:48**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:41
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:32:26
User entered '13:40'	(b) (4), (b) (6)	07 Jan 2021 16:32:26
	(b) (4)	
	Amber Stanford (b) (4)	28 Dec 2020 20:55:58
	(b) (4)	

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:00:48**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:41
User entered '28 Dec 2020 13:40'	System	28 Dec 2020 20:55:58

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:00:48**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:41
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:32:26
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 20:55:58

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 23:00:48**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:41
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:32:26
User entered 'Yes (Y)'	Amber Stanford (b) (4)	28 Dec 2020 20:55:58

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 1 (Day 1)'	(b) (4) Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '26 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:39:57
User closed query ' Per CDM: Response noted. Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. If the O2 Saturation and Temperature were not done, please consider recording these data points as "Not Done" individually. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 04:28:13
Query ' Per CDM: Response noted. Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. If the O2 Saturation and Temperature were not done, please consider recording these data points as "Not Done" individually. Thank you. ' answered with 'updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	21 Jan 2021 14:58:56
DataPoint Un-verified.	Amber Stanford (b) (4) (b) (4)	21 Jan 2021 14:58:47
User entered '0' reason for change: Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
User opened query ' Per CDM: Response noted. Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. If the O2 Saturation and Temperature were not done, please consider recording these data points as "Not Done" individually. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 09:38:00

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Query 'Per CDM: RQ: Response noted. Please consider to check 'Not done for O2 saturation' and 'Temperature' also consider to uncheck 'Assessment Not done' as other assessments are done except 'O2 saturation' and 'Temperature'. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:37:14
User opened query 'Per CDM: RQ: Response noted. Please consider to check 'Not done for O2 saturation' and 'Temperature' also consider to uncheck 'Assessment Not done' as other assessments are done except 'O2 saturation' and 'Temperature'. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:34:55
User closed query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 and 2. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:08:33
Query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 and 2. Please review and reconcile.' answered with 'No assessment for O2 and Temp' (Site from DM).	Amber Stanford (b) (4)	19 Jan 2021 23:09:29
User opened query 'Per CDM: Assessment Not Done is checked yet data is present for days 1 and 2. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 22:06:27
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered '1'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 20:57:35
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	21 Jan 2021 14:58:47
User entered empty.	System	28 Dec 2020 20:57:35

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Jan 2021 14:58:47
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:49:33
Query 'Per source, cough is mild.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:49:32
User opened query 'Per source, cough is mild.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:47:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:30
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Severe (Severe)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:57:35

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 2 (Day 2)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '27 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered '1'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 20:59:04
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	21 Jan 2021 14:58:47
User entered empty.	System	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 14:58:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 20:59:04
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04
	(b) (4)	

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	(b) (4), (b) (6)	28 Dec 2020 20:59:04
	Amber Stanford (b) (4)	
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 20:59:04

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 3 (Day 3)'	(b) (4) Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '098.7' F	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	28 Dec 2020 21:00:41

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 4 (Day 4)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '29 Dec 2020'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '99'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98.9' F	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:08:03

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 5 (Day 5)'	(b) (4) Kristin Pollock (b) (4) (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '30 Dec 2020'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98.4' F	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:10:01

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 6 (Day 6)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '31 Dec 2020'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '93'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:12:24

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '99.8' F	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Moderate (Moderate)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Form: Symptom Log (6)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:12:24

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**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 7 (Day 7)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '1 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '97.4' F	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:13:54

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 8 (Day 8)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '2 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98.0' F	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:14:59

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 9 (Day 9)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '3 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '99'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:16:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '97.6' F	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per source for 03JAN2021, patient did not have a runny nose present. ' (Site from CRA).	(b) (4)	14 Jan 2021 18:40:31
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 18:40:29
Query 'Per source for 03JAN2021, patient did not have a runny nose present. ' answered with 'Updated' (Site from CRA).	Amber Stanford (b) (4)	08 Jan 2021 21:33:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Jan 2021 21:33:12
User opened query 'Per source for 03JAN2021, patient did not have a runny nose present. ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:58:40
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:58:13
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per source for 03JAn2021, sore throat is noted to not be present but mild is selected. ' (Site from CRA).	(b) (4)	14 Jan 2021 18:40:41
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 18:40:34
Query 'Per source for 03JAn2021, sore throat is noted to not be present but mild is selected. ' answered with 'Reconciled' (Site from CRA).	Amber Stanford (b) (4)	08 Jan 2021 21:34:39
User opened query 'Per source for 03JAn2021, sore throat is noted to not be present but mild is selected. ' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:59:29
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:58:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:16:08

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 10 (Day 10)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '4 Jan 2021'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	04 Jan 2021 23:17:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '97.8' F	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Kristin Pollock (b) (4)	04 Jan 2021 23:17:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 11 (Day 11)'	(b) (4) Amber Stanford (b) (4)	05 Jan 2021 23:21:29

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '05 Jan 2021'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered '99'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	05 Jan 2021 23:21:29

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered '98.0' F	Amber Stanford (b) (4)	05 Jan 2021 23:21:29
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'Mild (Mild)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amber Stanford (b) (4)	05 Jan 2021 23:21:29

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 12 (Day 12)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '6 Jan 2021'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '0'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '98'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered '097.2' F	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 16:47:20
User entered 'None (None)'	Amy McMahan (b) (4)	06 Jan 2021 23:08:22

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 13 (Day 13)'	(b) (4) Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:04
User entered '07 Jan 2021'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:18
User entered '0'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:21
User entered '98'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	08 Jan 2021 21:55:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:19
User entered '97.2' F	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:25
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:27
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:32
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:35
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:38
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:41
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:33
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:30
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:44
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:36
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:39
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:48
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:51
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:43
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:49
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:06:46
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:03

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per CDM:RQ: Response provided as 'updated' however, data has not been updated yet. there is no data recorded for log line 15. Please verify and update data, else inactivate the log line or else provide clarification Thank you.' (Site from DM).	(b) (4)	22 Jan 2021 04:30:49
Query 'Per CDM:RQ: Response provided as 'updated' however, data has not been updated yet. there is no data recorded for log line 15. Please verify and update data, else inactivate the log line or else provide clarification Thank you.' (Site from DM).	Amber Stanford (b) (4)	21 Jan 2021 17:00:23
Query 'Per CDM:RQ: Response provided as 'updated' however, data has not been updated yet. there is no data recorded for log line 15. Please verify and update data, else inactivate the log line or else provide clarification Thank you.' answered with 'No data needed for line 15, which was previously inactivated on 19Jan2021.' (Site from DM).	(b) (4)	
User opened query 'Per CDM:RQ: Response provided as 'updated' however, data has not been updated yet. there is no data recorded for log line 15. Please verify and update data, else inactivate the log line or else provide clarification Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:54:08
User closed query 'Per CDM: It appears there is no data recorded for log line 15. Please verify and update data, else inactivate the log line.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:54:08
Query 'Per CDM: It appears there is no data recorded for log line 15. Please verify and update data, else inactivate the log line.' answered with 'Updated' (Site from DM).	Amber Stanford (b) (4)	19 Jan 2021 23:10:12
User opened query 'Per CDM: It appears there is no data recorded for log line 15. Please verify and update data, else inactivate the log line.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 22:09:22
User entered 'Day 14 (Day 14)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as 14 days of symptoms from illness Day 1 are expected per protocol, thanks.' (Site from CRA).	(b) (4)	09 Feb 2021 17:38:02
Query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as 14 days of symptoms from illness Day 1 are expected per protocol, thanks.' answered with 'Reconciled and symptom logs added' (Site from CRA).	Amber Stanford (b) (4)	03 Feb 2021 21:50:32
User opened query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as 14 days of symptoms from illness Day 1 are expected per protocol, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:35:19
User closed query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as expected per protocol, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 19:34:12
Query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as expected per protocol, thanks.' answered with 'Per protocol, patient had reached day 14 with resolution of all symptoms ' (Site from CRA).	Amber Stanford (b) (4)	28 Jan 2021 20:44:51
User opened query 'Per ETRTR: Please add log lines for Symptoms reported on 09Jan21 and 10Jan21 as expected per protocol, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:20:40
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 21:07:02
User entered '08 Jan 2021'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:10
User entered '0'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:06
User entered '99'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:05
User entered '97.6' F	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:12
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:15
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:19
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:27
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:13
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:23
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:29
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:17
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:33
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:25
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:21
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:36
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:40
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:38
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:31
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 23:00:48**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 21:07:35
User entered 'None (None)'	Amber Stanford (b) (4)	08 Jan 2021 21:55:46

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 15 (Day 15)'	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 21:49:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:49:50
User entered '09 Jan 2021' reason for change: Per Query Resolution	System	03 Feb 2021 21:49:50
User opened query 'Data is required. Please complete.' (Site from System).	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
User entered empty.	(b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	(b) (4)	19 Jan 2021 23:10:02

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered '0'	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4) Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	(b) (4) Amber Stanford (b) (4)	19 Jan 2021 23:10:02

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	03 Feb 2021 21:49:50
User entered empty.	System	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02

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Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Data Entry Error	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Data Entry Error	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (15)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4) Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4) Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:10:02

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Form: Symptom Log (15)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)' reason for change: Per Query Resolution	Amber Stanford (b) (4)	03 Feb 2021 21:49:50
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:28:51
DataPoint activated with code reason code Data required.	(b) (4)	
	Amber Stanford (b) (4)	03 Feb 2021 21:27:08
DataPoint inactivated with code reason code Data not required.	Amber Stanford (b) (4)	19 Jan 2021 23:10:02
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'Day 16 (Day 16)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered '10 Jan 2021'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered '0'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User entered '%'	System	03 Feb 2021 21:51:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

US3612031

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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Form: Symptom Log (16)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 23:00:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:50:56
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:39:57
User entered 'None (None)'	Amber Stanford (b) (4)	03 Feb 2021 21:51:20

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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**Form: COVID Diagnostic Test**

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[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered 'Yes (Y)'	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

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Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4)	
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE entered' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 05:03:00
DataPoint Verified.	Amber Stanford (b) (4)	19 Jan 2021 23:08:59
	(b) (4)	
User closed query 'Per CDM: Please keep the query open until result is updated.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:05:57
Query 'Per CDM: Please keep the query open until result is updated.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:41:29
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).	Amber Stanford (b) (4)	05 Jan 2021 23:01:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User opened query 'Per CDM: Please keep the query open until result is updated.' (Site from DM).	Amber Stanford (b) (4)	05 Jan 2021 23:01:10
Query 'Data is required. Please complete.' answered with 'Results pending' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 23:01:10
User entered empty; reason for change Data Entry Error	Amber Stanford (b) (4)	05 Jan 2021 23:01:10
User entered 'No (N)'	(b) (4)	
	Amber Stanford (b) (4)	28 Dec 2020 21:01:32
	(b) (4)	
	System	28 Dec 2020 21:01:24
	Amber Stanford (b) (4)	28 Dec 2020 21:01:24
	(b) (4)	
	Amber Stanford (b) (4)	28 Dec 2020 21:01:06
	(b) (4)	

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**Form: COVID Diagnostic Test**

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 21:01:06
	(b) (4)	

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**Form: COVID Diagnostic Test**

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered 'No (N)'	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 21:01:06
	Amber Stanford (b) (4)	
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Jan 2021 17:05:57
User entered empty.	Amber Stanford (b) (4)	28 Dec 2020 21:01:06

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:11
User entered '1'	System	05 Jan 2021 23:01:10
User entered '0'	System	28 Dec 2020 21:01:06

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Did the subject have Oxygen Saturation of  $SpO_2 \leq 93\%$  on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User closed query ' Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 6 (31DEC20), Kindly note "Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and also enter the oxygen saturation % or else clarify. Thanks' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Apr 2021 04:38:44
DataPoint Verified.	Richard Rupp (b) (4) (b) (4)	22 Apr 2021 15:29:50
Query ' Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 6 (31DEC20), Kindly note "Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and also enter the oxygen saturation % or else clarify. Thanks' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 19:22:54
DataPoint Un-verified.	Kristin Pollock (b) (4) (b) (4)	21 Apr 2021 19:20:35
Signature has been broken.	Kristin Pollock (b) (4)	21 Apr 2021 19:18:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Pollock (b) (4) (b) (4)	21 Apr 2021 19:18:49
User opened query ' Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 6 (31DEC20), Kindly note "Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections and also enter the oxygen saturation % or else clarify. Thanks' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 12:49:05
DataPoint Verified.	Richard Rupp (b) (4) (b) (4)	29 Mar 2021 16:45:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 19:02:40

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EAB) (1725)

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:25:13
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:50
DataPoint Un-verified.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
Signature has been broken.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User entered '31 Dec 2020' reason for change: Per Query Resolution	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User signature succeeded.	(b) (4) Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	(b) (4) Amber Stanford (b) (4)	20 Jan 2021 19:02:40

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:25:14
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:50
DataPoint Un-verified.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
Signature has been broken.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User entered '31 Dec 2020' reason for change: Per Query Resolution	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User signature succeeded.	(b) (4) Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	(b) (4) Amber Stanford (b) (4)	20 Jan 2021 19:02:40

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Form: Covid-19 Severity Assessment

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Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:25:17
User signature succeeded.	Richard Rupp (b) (4)	22 Apr 2021 15:29:50
DataPoint Un-verified.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
Signature has been broken.	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User entered '93' reason for change: Per Query Resolution	(b) (4) Kristin Pollock (b) (4)	21 Apr 2021 19:20:21
User signature succeeded.	(b) (4) Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	(b) (4) Amber Stanford (b) (4)	20 Jan 2021 19:02:40

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Generated On: 11 Aug 2021 23:00:48**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(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)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:02:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 19:02:57
User entered 'No (N)' reason for change: Data Entry Error	Amber Stanford (b) (4)	20 Jan 2021 19:02:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:02:40
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

**US3612031**

**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:48

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 19:02:40

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**Folder: Covid-19 Assessment 28 Dec 2020**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
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DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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**Generated On: 11 Aug 2021 23:00:48**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Generated On: 11 Aug 2021 23:00:48**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:48

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:02:40

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Folder: Covid-19 Assessment 28 Dec 2020

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Generated On: 11 Aug 2021 23:00:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:00:33
User entered empty.	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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**Folder: Covid-19 Assessment 28 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:27
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	01 Mar 2021 17:00:33
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 17:00:33
	(b) (4)	
	Amber Stanford (b) (4)	20 Jan 2021 19:02:40
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:00:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:51:35
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:24:51
User entered 'No (N)'	Amber Stanford (b) (4)	20 Jan 2021 19:03:15

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 3 (Day 3)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '28 Dec 2020'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 5 (Day 5)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	22 Feb 2021 10:28:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '915430603910' (Site from DM).	Amy McMahan (b) (4)	01 Feb 2021 20:27:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:55:59
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '30 Dec 2020'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 7 (Day 7)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	22 Feb 2021 10:28:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Tracking number 915430603910' (Site from DM).	Amy McMahan (b) (4)	01 Feb 2021 20:28:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:56:08
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '01 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 9 (Day 9)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44
	(b) (4)	

US3612031

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	22 Feb 2021 10:28:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Tracking number 915430603910' (Site from DM).	Amy McMahan (b) (4)	01 Feb 2021 20:28:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:56:16
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '03 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 14 (Day 14)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

US3612031

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	22 Feb 2021 10:28:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Tracking number 915430603910' (Site from DM).	Amy McMahan (b) (4)	01 Feb 2021 20:28:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:56:26
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '08 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 21 (Day 21)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44
	(b) (4)	

US3612031

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	22 Feb 2021 10:28:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Tracking number 915430603910' (Site from DM).	Amy McMahan (b) (4)	01 Feb 2021 20:28:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:56:35
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '15 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User accepted default value 'Day 28 (Day 28)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

US3612031

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:00:48

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:10
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Query 'Per GCL Lab Recon: saliva: requery 1: the "day 28" is missing in Central lab for 22JAN2021,' canceled (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:36:00
User opened query 'Per GCL Lab Recon: saliva: requery 1: the "day 28" is missing in Central lab for 22JAN2021,' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:35:58
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample updated in PPD Central lab has missing saliva day for 22JAN2021, please update preclarus via DCF to update the day as Day 28.Thanks' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:35:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample updated in PPD Central lab has missing saliva day for 22JAN2021, please update preclarus via DCF to update the day as Day 28.Thanks' answered with 'Please clarify what is needed. ' (Site from DM).	Amy McMahan (b) (4)	02 Mar 2021 17:43:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample updated in PPD Central lab has missing saliva day for 22JAN2021, please update preclarus via DCF to update the day as Day 28.Thanks' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:33:41
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:28:34

US3612031

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:00:48

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Tracking number 915430603910' (Site from DM).	Amy McMahan (b) (4) (b) (4)	01 Feb 2021 20:28:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22JAN2021 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:56:44
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 16:29:31
User entered '22 Jan 2021'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:12:44

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:49
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:46
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:49
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:46
User entered '28 Dec 2020'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:49
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:46
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:49
User entered 'SICKD1'	System	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered 'Yes (Y)'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '13:49'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User entered '28 Dec 2020 13:49'	System	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
DataPoint set to visible.	(b) (4) System	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
DataPoint set to visible.	(b) (4) System	28 Dec 2020 21:08:21

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '098.7' F	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered empty.	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '087'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User entered 'bpm'	System	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '016'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User entered 'breaths/min'	System	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '136'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User entered 'mmHg'	System	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered '091'	Amber Stanford (b) (4)	28 Dec 2020 21:09:15
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53
User entered 'mmHg'	System	28 Dec 2020 21:09:15

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:53

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:58
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:15:59
User entered 'Yes (Y)'	Amber Stanford (b) (4)	28 Dec 2020 21:09:25
	(b) (4)	

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:19:58
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:15:59
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:09:25
	(b) (4)	

US3612031

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:00:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:03
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:16:12
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	28 Dec 2020 21:09:36

**US3612031**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:20:03
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:12
User entered '28 Dec 2020'	Amber Stanford (b) (4)	28 Dec 2020 21:09:36
	(b) (4)	

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:22
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:26:18
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:04:09

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:22
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:26:18
User entered '22 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:04:09
	(b) (4)	

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:22
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:26:18
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	22 Jan 2021 19:04:09

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:22
User entered 'SICKD28'	System	22 Jan 2021 19:04:09

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered '22 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13
	(b) (4)	

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered '11:02'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User entered '22 Jan 2021 11:02'	System	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	22 Jan 2021 19:09:13
DataPoint set to visible.	(b) (4) System	22 Jan 2021 19:04:09

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered missing code ND - Not Done.	Amber Stanford (b) (4)	22 Jan 2021 19:09:13
DataPoint set to visible.	(b) (4) System	22 Jan 2021 19:04:09

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered '098.6' F	Amber Stanford (b) (4)	22 Jan 2021 19:09:13
	(b) (4)	

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered empty.	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered '062'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User entered 'bpm'	System	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered '016'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User entered 'breaths/min'	System	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:07
User entered '120'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User entered 'mmHg'	System	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:27:07
User entered '83'	Amber Stanford (b) (4)	22 Jan 2021 19:09:13
	(b) (4)	

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30
User entered 'mmHg'	System	22 Jan 2021 19:09:13

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:30

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:36
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:27:26
User entered 'Yes (Y)'	Amber Stanford (b) (4)	22 Jan 2021 19:09:25

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:36
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 16:27:26
User entered '22 Jan 2021'	Amber Stanford (b) (4)	22 Jan 2021 19:09:25
	(b) (4)	

US3612031

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:00:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:34
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:09:37

**US3612031**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:39:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:34
User entered '22 Jan 2021'	Amber Stanford (b) (4) (b) (4)	22 Jan 2021 19:09:37

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:06
User entered 'Yes (Y)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:22

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:06
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:57:22
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:06
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:22
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 16:57:22

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:15:41
User entered '29 Jan 2021'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:40:49
User entered '0'	Amber Stanford (b) (4)	08 Mar 2021 19:38:09
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 19:03:34

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:15:41
User entered 'Yes (Y)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:41:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	Amber Stanford (b) (4)	08 Mar 2021 19:38:09
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 19:03:34

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:15:41
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:15:41
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:15:41
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:15:41
User entered 'Placebo (Placebo)'	Amber Stanford (b) (4)	29 Jan 2021 16:57:51
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:15:41
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '1'	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered empty.	System	29 Jan 2021 16:58:46
DataPoint set to visible.	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered empty.	System	29 Jan 2021 16:58:46
DataPoint set to visible.	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered 'Yes (Y)'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered '10:37'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '29 Jan 2021 10:37'	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '098.7' F	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:16:58
	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '093'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'bpm'	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '016'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'breaths/min'	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '131'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '085'	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered missing code ND - Not Done.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered empty.	System	29 Jan 2021 16:58:46
DataPoint set to visible.	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 17:23:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 17:23:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 17:23:38
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 16:58:46
User entered empty.	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '29 Jan 2021' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered '11:17' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '29 Jan 2021 11:17'	System	29 Jan 2021 17:23:38
User entered empty.	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '098.5' F reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered empty.	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '089' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'bpm'	System	29 Jan 2021 17:23:38
User entered empty.	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered '016' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'breaths/min'	System	29 Jan 2021 17:23:38
User entered empty.	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:16:58
User entered '129' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	29 Jan 2021 17:23:38
User entered empty.	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:16:58
User entered '081' reason for change: Data Entry Error	Amber Stanford (b) (4)	29 Jan 2021 17:23:38
User entered empty.	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:46
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	29 Jan 2021 17:23:38
User entered empty.	System	29 Jan 2021 16:58:46

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:26
User entered 'No (N)'	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:52
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:26
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:17:26
	(b) (4)	
	Amber Stanford (b) (4)	29 Jan 2021 16:58:52
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:36
User entered 'Yes (Y)'	Amber Stanford (b) (4)	29 Jan 2021 16:59:10

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:36
User entered empty.	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	29 Jan 2021 16:59:10
	(b) (4)	

US3612031

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

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 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:36
User entered empty.	(b) (4), (b) (6)	
	Amber Stanford (b) (4)	29 Jan 2021 16:59:10
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mRNA-1273'	System	29 Jan 2021 16:59:10
DataPoint set to visible.	System	29 Jan 2021 16:57:51

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:17:36
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:59:10
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:17:36
User entered '10:45'	Amber Stanford (b) (4)	29 Jan 2021 16:59:10

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '29 Jan 2021 10:45'	System	29 Jan 2021 16:59:10

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:17:36
User entered 'Left Arm (LEFT ARM)'	Amber Stanford (b) (4)	29 Jan 2021 16:59:10
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 17:17:36
User entered 'ONCE'	System	29 Jan 2021 16:59:10

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'INTRAMUSCULAR'	System	29 Jan 2021 16:59:10

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:18:00
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:59:28

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:18:00
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:59:28
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 17:18:00
User entered '10:10'	Amber Stanford (b) (4)	29 Jan 2021 16:59:28
	(b) (4)	

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '29 Jan 2021 10:10'	System	29 Jan 2021 16:59:28

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:18:13
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	29 Jan 2021 16:59:41

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:18:13
User entered '29 Jan 2021'	Amber Stanford (b) (4)	29 Jan 2021 16:59:41

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:18:13
User entered '10:14'	Amber Stanford (b) (4)	29 Jan 2021 16:59:41

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:48**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '29 Jan 2021 10:14'	System	29 Jan 2021 16:59:41

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 17:18:17
User entered 'Yes (Y)'	Amber Stanford (b) (4)	29 Jan 2021 16:59:48

**US3612031**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	29 Jan 2021 16:59:48

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	12 Mar 2021 18:22:08
User entered 'Yes (Y)'	Amber Stanford (b) (4)	08 Feb 2021 21:02:24

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:08
User entered '08 Feb 2021'	Amber Stanford (b) (4)	08 Feb 2021 21:02:24
	(b) (4)	

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:22:08
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	08 Feb 2021 21:02:24

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	12 Mar 2021 18:22:08
User entered empty.	Amber Stanford (b) (4)	08 Feb 2021 21:02:24

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:15
User entered 'Yes (Y)'	Amber Stanford (b) (4)	08 Feb 2021 21:02:28
	(b) (4)	

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	08 Feb 2021 21:02:28

**US3612031**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	08 Feb 2021 21:02:28
DataPoint set to visible.	System	08 Feb 2021 21:02:28

**US3612031**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	12 Mar 2021 18:22:32
User entered 'Yes (Y)'	Amber Stanford (b) (4)	26 Feb 2021 17:15:11

**US3612031**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:32
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 17:15:11
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:22:32
User entered 'Clinic (Clinic)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:15:11

**US3612031**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'OLD29'	System	26 Feb 2021 17:15:11

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered 'Yes (Y)'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '10:18'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '26 Feb 2021 10:18'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '098.1' F	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	12 Mar 2021 18:22:56
User entered empty.	Amber Stanford (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '075'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'bpm'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '016'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'breaths/min'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '125'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '081'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '11:07'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '26 Feb 2021 11:07'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '098.1' F	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered 'Oral (Oral)'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered empty.	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '079'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'bpm'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '016'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'breaths/min'	System	26 Feb 2021 17:30:45

US3612031

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '126'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:22:56
User entered '079'	Amber Stanford (b) (4)	26 Feb 2021 17:30:45
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mmHg'	System	26 Feb 2021 17:30:45

**US3612031**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:24
User entered 'Yes (Y)'	Amber Stanford (b) (4)	26 Feb 2021 17:31:07
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:24
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 17:31:07
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered 'Yes (Y)'	Amber Stanford (b) (4)	26 Feb 2021 17:31:33
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered empty.	Amber Stanford (b) (4)	26 Feb 2021 17:31:33
	(b) (4)	

US3612031

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:48

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 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered empty.	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:31:33

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'mRNA-1273'	System	26 Feb 2021 17:31:33
DataPoint set to visible.	System	08 Feb 2021 21:02:28

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered '26 Feb 2021'	Amber Stanford (b) (4)	26 Feb 2021 17:31:33
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered '10:35'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:31:33

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered '26 Feb 2021 10:35'	System	26 Feb 2021 17:31:33

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered 'Left Arm (LEFT ARM)'	Amber Stanford (b) (4)	26 Feb 2021 17:31:33
	(b) (4)	

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:23:34
User entered 'ONCE'	System	26 Feb 2021 17:31:33

**US3612031**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:48**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 17:31:33

**US3612031**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:23:40
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	26 Feb 2021 17:31:39

**US3612031**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	26 Feb 2021 17:31:39

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:23:52
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 21:14:49

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:52
User entered '05 Mar 2021'	Amber Stanford (b) (4)	09 Mar 2021 21:14:49
	(b) (4)	

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:23:52
User entered 'Contact Made (CONTACT MADE)'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 21:14:49

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:23:52
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 21:14:49
	(b) (4)	

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:24:00
User entered 'Yes (Y)'	Amber Stanford (b) (4)	09 Mar 2021 21:14:53
	(b) (4)	

**US3612031**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:57
User entered 'I'	System	09 Mar 2021 21:14:53

**US3612031**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:32

**US3612031**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered '30 Mar 2021'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:32

**US3612031**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Clinic (Clinic)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:32

**US3612031**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:48**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 17:57:32

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered empty.	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:57:38

**US3612031**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'No (N)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 17:57:45

**US3612031**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:48**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
	(b) (4)	
User entered empty.	Amber Stanford (b) (4)	30 Mar 2021 17:57:45
	(b) (4)	

**US3612031**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
User entered 'Yes (Y)'	(b) (4) Amber Stanford (b) (4) (b) (4)	30 Mar 2021 18:00:13

**US3612031**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
	(b) (4)	
User entered '30 Mar 2021'	Amber Stanford (b) (4)	30 Mar 2021 18:00:13
	(b) (4)	

**US3612031**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	31 Mar 2021 21:10:46
	(b) (4)	
User entered '09:18'	Amber Stanford (b) (4)	30 Mar 2021 18:00:13
	(b) (4)	

**US3612031**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:18'	System	30 Mar 2021 18:00:13

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 23:00:48**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:06:16
User signature succeeded.	Richard Rupp (b) (4)	19 Mar 2021 16:14:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 15:33:06
User entered 'Yes (Y)'	Amy McMahan (b) (4)	28 Sep 2020 21:53:32
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4)	
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'YES' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:42:54
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 22:01:51
User coded data point as SOC: Infections and infestations, HLT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Amy McMahan (b) (4)	01 Feb 2021 07:58:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	(b) (4), (b) (6)	07 Jan 2021 17:16:46
User entered 'Sinus Infection'		
	(b) (4), (b) (6)	18 Dec 2020 17:34:48
	Coder Import (b) (4)	
	(b) (4)	
	Coder Import (b) (4)	18 Dec 2020 17:34:48
	(b) (4)	
	System	18 Dec 2020 16:53:35
	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:48
User entered 'Yes (Y)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '18 Sep 2020'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User entered empty.	System	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '28 Sep 2020'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User entered empty.	System	18 Dec 2020 16:53:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 16:53:17
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	18 Dec 2020 16:53:17
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:02
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 16:53:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	18 Dec 2020 16:53:36
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:02
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 16:53:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	18 Dec 2020 16:53:36
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 16:53:02
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 16:53:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 16:53:36
User entered 'None (NONE)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	18 Dec 2020 16:53:36
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 16:53:02
User entered empty.	System	18 Dec 2020 16:53:02
	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
Signature has been broken.	(b) (4)	
	Amy McMahan (b) (4)	07 Apr 2021 15:17:21
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'l'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Kristin Pollock (b) (4)	18 Dec 2020 16:53:02
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User entered '0'	System	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03
User entered 'I'	System	18 Dec 2020 16:53:02

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:16:03

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:47:56
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'Per patient report, no underlying medical condition or diagnosis noted.' (Site from DM).	Amber Stanford (b) (4) (b) (4)	10 Feb 2021 22:40:19
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:00:27
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:47:23
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'YES' (Site from DM).	Amy McMahan (b) (4) (b) (4)	01 Feb 2021 22:01:59
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:58:14
User closed query 'Please add COVID+ diagnosis to AE log.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 17:57:45
Query 'Please add COVID+ diagnosis to AE log.' answered with 'updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:06:12
User opened query 'Please add COVID+ diagnosis to AE log.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:19:53
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:16:59

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Wheezing, LLT: Wheezing - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 22:58:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 22:58:32
Data point term sent to Coder	System	05 Jan 2021 22:58:11
User entered 'Wheezing'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:18:22
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 17:18:18
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered 'Yes (Y)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '23 Oct 2020'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User entered empty.	System	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'No (N)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered '09 Nov 2020'	Amber Stanford (b) (4) (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User entered empty.	System	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered 'No (N)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
Query 'Source states NONE.' canceled (Site from CRA).	(b) (4)	15 Mar 2021 17:23:19
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 17:23:17
User opened query 'Source states NONE.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:26:21
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:51:56
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'updated' (Site from DM).	Amber Stanford (b) (4)	19 Jan 2021 23:06:48
DataPoint Un-verified.	Amber Stanford (b) (4)	19 Jan 2021 23:06:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Amber Stanford (b) (4)	19 Jan 2021 23:06:42
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 13:24:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 22:58:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 22:58:14
User entered 'None (NONE)' reason for change: Data Entry Error	Amber Stanford (b) (4)	05 Jan 2021 22:58:14
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 22:57:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered 'l'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered '0'	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:16:59
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 22:58:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 22:58:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amber Stanford (b) (4)	05 Jan 2021 22:58:21
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 22:57:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4) (b) (4)	05 Jan 2021 22:57:59

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	07 Jan 2021 17:16:59
User entered empty.	Amber Stanford (b) (4)	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User entered '0'	System	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24
User entered 'I'	System	05 Jan 2021 22:57:59

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:24

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:26:40
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:36:59
User entered		
'USA-US129-2021-mRNA-1273-P301000003'	System	12 Jan 2021 17:36:54
User entered 'New'	(b) (4), (b) (6)	12 Jan 2021 17:36:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
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.	(b) (4) Coder Import (b) (4)	12 Jan 2021 19:09:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 19:09:57
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:16:28
Data point term sent to Coder	System	11 Jan 2021 19:29:54
User entered 'SMPTOMATIC COVID-19'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Patient seen in office for unscheduled visit, thus receiving medical attention. Please review data and consider this answer.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:42:14
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:42:12
Query 'Patient seen in office for unscheduled visit, thus receiving medical attention. Please review data and consider this answer.' answered with 'updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	15 Mar 2021 18:41:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	15 Mar 2021 18:41:15
User opened query 'Patient seen in office for unscheduled visit, thus receiving medical attention. Please review data and consider this answer.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:28:14
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:26:57
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:26:59
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:16:32
User entered '26 Dec 2020'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:19
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:23
DataPoint Un-verified.	Amber Stanford (b) (4)	19 Jan 2021 23:08:39
User entered 'No (N)' reason for change: New Information	(b) (4) Amber Stanford (b) (4)	19 Jan 2021 23:08:39
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:16:34
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:30
User entered '08 Jan 2021' reason for change: New Information	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:08:39
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:32
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 20:16:37
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:39
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:40
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:44
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

US3612031

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:49
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:54
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:29:07
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:42
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:47
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:52
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:29:05
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:28:56
User entered 'Not Related (NOT RELATED)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:29:27
User entered 'Not Related (NOT RELATED)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:29:19
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 08:52:25
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:07:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:07:05
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 13:24:58
User entered 'None (NONE)'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Source states NONE.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:42:56
	(b) (4), (b) (6)	17 Mar 2021 15:42:51
Query 'Source states NONE.' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4)	15 Mar 2021 18:41:34
User entered '1' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Amber Stanford (b) (4)	15 Mar 2021 18:41:15
	(b) (4), (b) (6)	12 Mar 2021 18:30:04
User opened query 'Source states NONE.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:30:02
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:29:30
User entered '0' reason for change: Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 16:47:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	11 Jan 2021 19:29:54
	Amy McMahan (b) (4)	11 Jan 2021 19:29:54
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '0'	System	11 Jan 2021 19:29:32
	Amy McMahan (b) (4)	11 Jan 2021 19:29:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Source states NONE.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:42:58
	(b) (4), (b) (6)	17 Mar 2021 15:42:54
Query 'Source states NONE.' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4)	15 Mar 2021 18:41:39
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amber Stanford (b) (4)	15 Mar 2021 18:41:15
User opened query 'Source states NONE.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:30:10
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amber Stanford (b) (4)	21 Jan 2021 16:47:11
User entered '0'	(b) (4)	
	Amy McMahan (b) (4)	11 Jan 2021 19:29:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:22
User entered '0'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Amber Stanford (b) (4) (b) (4)	19 Jan 2021 23:08:39
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:29:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 19:29:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:46
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:29:32
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:28
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:55:37
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 'Updated' (Site from Safety).	Amber Stanford (b) (4) (b) (4)	21 Jan 2021 16:48:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:18:14
User entered empty.	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 19:29:32

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 18:41:15
User entered '0'	System	11 Jan 2021 19:29:32

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:30:39
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 19:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	02 Mar 2021 19:57:46
Data point term sent to Coder	System	02 Mar 2021 19:56:44
User entered 'Tachycardia'	Amber Stanford (b) (4)	02 Mar 2021 19:56:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:41
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:30:58
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:00
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:03
User entered '12 Feb 2021'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:05
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:07
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

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Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:19
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Mar 2021 19:56:55
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	02 Mar 2021 19:56:55
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Mar 2021 19:56:33
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:17
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:13
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:21
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:29
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:27
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:34
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:39
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:31
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:24
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:42
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:44
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:48
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:36
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:31:46
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Source states NONE but the event occurred post patients receipt of 2nd dose, thus no action can be taken and N/A applies. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:43:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:43:37
Query 'Source states NONE but the event occurred post patients receipt of 2nd dose, thus no action can be taken and N/A applies. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	15 Mar 2021 18:43:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amber Stanford (b) (4) (b) (4)	15 Mar 2021 18:42:55
User opened query 'Source states NONE but the event occurred post patients receipt of 2nd dose, thus no action can be taken and N/A applies. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:34:15
DataPoint Un-verified.	(b) (4), (b) (6)	12 Mar 2021 18:32:00
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:31:50
User entered 'None (NONE)'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:34:20
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

US3612031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 04:04:20
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Reconciled and updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:43:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 23:37:50
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:34:22
User entered 'I'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:34:29
User entered '0'	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
	(b) (4)	
User closed query 'Source states Recovered/reosolved.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:43:45
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:43:43
	(b) (4), (b) (6)	
Query 'Source states Recovered/reosolved.' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4)	15 Mar 2021 18:43:25
	(b) (4)	
User opened query 'Source states Recovered/reosolved.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:34:49
	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Amber Stanford (b) (4)	02 Mar 2021 19:56:55
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amber Stanford (b) (4)	02 Mar 2021 19:56:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:35:11
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:35:14
User entered empty.	Amber Stanford (b) (4) (b) (4)	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 19:56:33

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User closed query 'Per DM CLR: Please review and determine if AE #9 (MUSCLE SPASMS: 13-16JAN2021) should be is related and should be combined with this AE, as this event is the same CTCAE grade and start date. If yes, combine into one medical condition. Update eCRF as appropriate. Else, confirm events are not related.' (Site from DM). Query 'Per DM CLR: Please review and determine if AE #9 (MUSCLE SPASMS: 13-16JAN2021) should be is related and should be combined with this AE, as this event is the same CTCAE grade and start date. If yes, combine into one medical condition. Update eCRF as appropriate. Else, confirm events are not related.' answered with 'spasms were a result of neck pain. Spasms removed.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:02:27
User opened query 'Per DM CLR: Please review and determine if AE #9 (MUSCLE SPASMS: 13-16JAN2021) should be is related and should be combined with this AE, as this event is the same CTCAE grade and start date. If yes, combine into one medical condition. Update eCRF as appropriate. Else, confirm events are not related.' (Site from DM).	Amy McMahan (b) (4)	07 Apr 2021 15:19:41
User signature succeeded.	(b) (4)	
User opened query 'Per DM CLR: Please review and determine if AE #9 (MUSCLE SPASMS: 13-16JAN2021) should be is related and should be combined with this AE, as this event is the same CTCAE grade and start date. If yes, combine into one medical condition. Update eCRF as appropriate. Else, confirm events are not related.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:16:44
DataPoint Verified.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
	(b) (4), (b) (6)	23 Mar 2021 17:59:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 19:50:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 19:50:53
Data point term sent to Coder	System	18 Mar 2021 19:35:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:48

[Adverse event](#)

Audit	User	Time (GMT)
Query 'CDM Coding, please split the term (NECK PAIN WITH MUSCLE SPASM) into two separate records, as 'NECK PAIN' and 'MUSCLE SPASM' reporting each term separately with all relevant information e.g. start and stop dates etc. ' canceled (Site from System).	Coder Import (b) (4)	18 Mar 2021 19:34:53
Data point term sent to Coder	System	18 Mar 2021 19:34:16
DataPoint Un-verified.	Amber Stanford (b) (4)	18 Mar 2021 19:33:31
User entered 'NECK PAIN' reason for change: Data Entry Error	Amber Stanford (b) (4)	18 Mar 2021 19:33:31
User opened query 'CDM Coding, please split the term (NECK PAIN WITH MUSCLE SPASM) into two separate records, as 'NECK PAIN' and 'MUSCLE SPASM' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4)	18 Mar 2021 17:57:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:36:09
Data point term sent to Coder	System	09 Mar 2021 20:22:13
User entered 'Neck pain with muscle spasm'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:13
User entered 'Yes (Y)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:16
User entered 'No (N)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:36:18
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:22
User entered '13 Jan 2021'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:24
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User entered empty.	System	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:27
User entered 'No (N)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:30
User entered '16 Jan 2021'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:33
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User entered empty.	System	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:36:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:41
User entered 'No (N)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:43
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:52
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:36:59
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:03
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:07
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:09
User entered empty.	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:36:45
User entered empty.	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:36:54
User entered '0'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:12
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:17
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:37:20
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:24
User entered 'Not Related (NOT RELATED)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:28
User entered 'Not Applicable (NOT APPLICABLE)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:29
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:32
User entered 'l'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 18:37:35
User entered '0'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
Query 'Source has no outcome selected.' canceled (Site from CRA).	(b) (4)	15 Mar 2021 17:23:53
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 17:23:51
User opened query 'Source has no outcome selected.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 18:38:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amber Stanford (b) (4)	09 Mar 2021 20:21:52
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:41
User entered empty.	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User signature succeeded.	Richard Rupp (b) (4)	25 Mar 2021 17:25:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:43
User entered empty.	Amber Stanford (b) (4) (b) (4)	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User entered '0'	System	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04
User entered 'I'	System	09 Mar 2021 20:21:52

**US3612031**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:37:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:00:48

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:06:16
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:13:01
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Per subject answer submitted was an error' (Site from DM).	Amber Stanford (b) (4) (b) (4)	28 Jan 2021 22:04:52
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 07:53:48
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:05
User entered 'Yes (Y)'	Amy McMahan (b) (4) (b) (4)	10 Sep 2020 15:08:06

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:05:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 19:05:56
Data point term sent to Coder	System	28 Oct 2020 21:03:24
Coding entries removed.	Amber Stanford (b) (4)	28 Oct 2020 21:02:48
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:10:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:10:38
Data point term sent to Coder	System	10 Sep 2020 15:09:59
User entered 'indomethacin'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User closed query 'No answer selected in source. ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 15:33:30
Query 'No answer selected in source. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 21:59:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 21:58:47
User opened query 'No answer selected in source. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:51:43
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 16:51:29
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'Yes (Y)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication as appropriate and ensure indication is reconciled with any corresponding MH or AE. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:48:56
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication as appropriate and ensure indication is reconciled with any corresponding MH or AE. ' answered with 'Medical history reconciled and indication updated' (Site from DM).	Amber Stanford (b) (4)	28 Oct 2020 21:03:45
DataPoint Un-verified.	(b) (4)	28 Oct 2020 21:02:48
User entered 'Osteoarthritis of bilateral knees' reason for change: Data Entry Error	Amber Stanford (b) (4)	28 Oct 2020 21:02:48
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication as appropriate and ensure indication is reconciled with any corresponding MH or AE. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:26:26
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'arthritis'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered '50'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'mg (mg)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	23 Sep 2020 16:50:16
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'as needed (PRN)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	23 Sep 2020 16:50:16
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	23 Sep 2020 16:50:16
User entered empty.	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	23 Sep 2020 16:50:16
User entered '6 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered '0'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	23 Sep 2020 16:50:16
User entered '06 Sep 2020'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'No answer in source. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 15:33:34
Query 'No answer in source. ' answered with 'Updated' (Site from CRA).	Amy McMahan (b) (4)	28 Sep 2020 21:58:46
	(b) (4)	
User opened query 'No answer in source. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:51:58
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 16:50:16
User entered 'No (N)'	Amy McMahan (b) (4)	10 Sep 2020 15:09:04
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User entered empty.	System	10 Sep 2020 15:09:04

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User entered empty.	System	10 Sep 2020 15:09:04

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:25
User entered empty.	System	10 Sep 2020 15:09:04

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:37:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:37:38
Data point term sent to Coder	System	07 Oct 2020 16:36:23
User entered 'Bactrim'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'No (N)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per CDM: Requery: Kindly update AE for sinus infection after receiving response from PI. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 03:44:12
Query 'Per CDM: Requery: Kindly update AE for sinus infection after receiving response from PI. Thank you.' answered with 'AE updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	18 Dec 2020 16:59:24
User opened query 'Per CDM: Requery: Kindly update AE for sinus infection after receiving response from PI. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:29:11
User closed query 'Per CDM Re-Query: Please note that HEADACHE was confirmed not be reportable as AE. Please confirm Sinus Infections should be reported as this is not a SAR. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:26:49
Query 'Per CDM Re-Query: Please note that HEADACHE was confirmed not be reportable as AE. Please confirm Sinus Infections should be reported as this is not a SAR. Thank you' answered with 'Source doc updated with AE and awaiting PI signature to determine causality; will then update EDC with sinus infection AE ' (Site from DM).	Amber Stanford (b) (4) (b) (4)	15 Dec 2020 19:58:38
User opened query 'Per CDM Re-Query: Please note that HEADACHE was confirmed not be reportable as AE. Please confirm Sinus Infections should be reported as this is not a SAR. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:24:24

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:24:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Amy McMahan (b) (4)	07 Dec 2020 17:38:08
' answered with 'not reportable' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4), (b) (6)	24 Nov 2020 14:03:04
' (Site from DM).		

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this is a combination drug. Please update the dose entry for this medication to list the specific doses for each component (e.g., Dose=800/160; Dose Unit=milligram). Please update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:01:44
User opened query 'Per DM CLR: Please note that this is a combination drug. Please update the dose entry for this medication to list the specific doses for each component (e.g., Dose=800/160; Dose Unit=milligram). Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:01:32
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'SINUS INFECTION'	Amy McMahan (b) (4) (b) (4)	07 Oct 2020 16:35:35

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Source states 160, Please update source and/or EDC.' (Site from CRA).	(b) (4)	
Query 'Source states 160, Please update source and/or EDC.' answered with 'reconciled and updated' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 17:58:27
DataPoint Verified.	Amber Stanford (b) (4)	19 Jan 2021 23:11:54
	(b) (4)	
User opened query 'Source states 160, Please update source and/or EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 20:22:13
User closed query 'Per DM CLR: Please note that this is a combination drug. Please update the dose entry for this medication to list the specific doses for each component (e.g., Dose=800/160; Dose Unit= milligram). Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:21:41
Query 'Per DM CLR: Please note that this is a combination drug. Please update the dose entry for this medication to list the specific doses for each component (e.g., Dose=800/160; Dose Unit= milligram). Please update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:22:39
DataPoint Un-verified.		
User entered '800/160' reason for change: Data Entry Error	Amy McMahan (b) (4)	07 Dec 2020 17:39:04
User opened query 'Per DM CLR: Please note that this is a combination drug. Please update the dose entry for this medication to list the specific doses for each component (e.g., Dose=800/160; Dose Unit= milligram). Please update eCRF as appropriate. ' (Site from DM).	(b) (4)	
DataPoint Verified.	Amy McMahan (b) (4)	07 Dec 2020 17:38:57
	(b) (4)	
User entered '160'	Amy McMahan (b) (4)	07 Dec 2020 17:38:57
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:01:57
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'mg (mg)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'twice daily (BID)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4) (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered '19 Sep 2020'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered '0'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 15:09:57
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:09:52
DataPoint Un-verified.	Amber Stanford (b) (4)	22 Oct 2020 19:05:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 19:05:38
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'Yes (Y)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User closed query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:09:59
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		22 Oct 2020 19:05:38
User entered '28 Sep 2020' reason for change: Data Entry Error	Amber Stanford (b) (4)	22 Oct 2020 19:05:38
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	21 Oct 2020 22:09:41
Query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' answered by data change (Site from CRA).	System	21 Oct 2020 22:09:41
DataPoint Un-verified.	Kristin Pollock (b) (4)	21 Oct 2020 22:09:41
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 22:09:41
User opened query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' (Site from CRA).	Kristin Pollock (b) (4)	20 Oct 2020 20:36:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:35:35
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered 'No (N)'	Amy McMahan (b) (4)	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User entered '2'	System	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User entered '1'	System	07 Oct 2020 16:35:35

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:29
User entered '804 (804)'	System	07 Oct 2020 16:35:35

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:39:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:39:56
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31
Data point term sent to Coder	System	07 Oct 2020 16:38:25
User entered 'MONTELUKAST'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'No (N)'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per CDM: Requery: Kindly consider to update EDC for SINUS INFECTION after receiving response from PI. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 03:44:48
Query 'Per CDM: Requery: Kindly consider to update EDC for SINUS INFECTION after receiving response from PI. Thank you.' answered with 'AE updated' (Site from DM).	Amber Stanford (b) (4) (b) (4)	18 Dec 2020 16:59:43
User opened query 'Per CDM: Requery: Kindly consider to update EDC for SINUS INFECTION after receiving response from PI. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:31:05
User closed query 'Per CDM Re-Query: It was confirmed that HEADACHE was not reportable. Please confirm if this SINUS INFECTION should be reported as this is not a SAR. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:27:47
Query 'Per CDM Re-Query: It was confirmed that HEADACHE was not reportable. Please confirm if this SINUS INFECTION should be reported as this is not a SAR. Thank you' answered with 'Source doc updated with AE and awaiting PI signature to determine causality; will then update EDC with sinus infection AE ' (Site from DM).	Amber Stanford (b) (4) (b) (4)	15 Dec 2020 19:59:18
User opened query 'Per CDM Re-Query: It was confirmed that HEADACHE was not reportable. Please confirm if this SINUS INFECTION should be reported as this is not a SAR. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:25:26

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:48

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:25:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Amy McMahan (b) (4)	07 Dec 2020 17:39:26
' answered with 'not reportable' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4), (b) (6)	24 Nov 2020 13:02:38
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:38:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Indication](#)

Audit	User	Time (GMT)
User entered 'SINUS INFECTION'	Amy McMahan (b) (4) (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered '10'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'mg (mg)'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'once daily (QD)'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4) (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 16:38:31
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered '19 Sep 2020'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered '0'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User closed query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:10:40
Query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' answered by data change (Site from CRA).	System	21 Oct 2020 22:10:32
DataPoint Un-verified.	Kristin Pollock (b) (4)	21 Oct 2020 22:10:32
User entered 'No (N)' reason for change: New Information	(b) (4)	21 Oct 2020 22:10:32
User opened query 'Per D22 safety call source the patient has stopped the medication. Please obtain an end date and update source and EDC. ' (Site from CRA).	Kristin Pollock (b) (4)	21 Oct 2020 22:10:32
DataPoint Verified.	(b) (4)	20 Oct 2020 20:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:38:31
	(b) (4)	07 Oct 2020 16:37:38

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
DataPoint Un-verified.	Kristin Pollock (b) (4)	21 Oct 2020 22:10:32
User entered '22 Sep 2020' reason for change: Data Entry Error	Kristin Pollock (b) (4)	21 Oct 2020 22:10:32
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered empty.	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	07 Oct 2020 16:38:31
User entered 'No (N)'	Amy McMahan (b) (4)	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User entered '1'	System	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User entered '1'	System	07 Oct 2020 16:37:38

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:37
User entered '804 (804)'	System	07 Oct 2020 16:37:38

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Con med list has listed Medrol dosepak that was not taken prophylactically or for a SAR and is not a vaccine, it was taken from 02-07NOV2020, 4mg PO as directed X 6 days. Excedrin was not taken prophylactically or for a SAR and is not a vaccine, it ia ongoing starting from 26DEC2020, 325/500/65mg PO BID. Please ensure that all con meds listed in source are also documented in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:15:33
Query 'Con med list has listed Medrol dosepak that was not taken prophylactically or for a SAR and is not a vaccine, it was taken from 02-07NOV2020, 4mg PO as directed X 6 days. Excedrin was not taken prophylactically or for a SAR and is not a vaccine, it ia ongoing starting from 26DEC2020, 325/500/65mg PO BID. Please ensure that all con meds listed in source are also documented in EDC.' answered with 'Reconciled and confirmed all con meds and AEs within EDC and source.' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	20 Jan 2021 16:26:44
User opened query 'Con med list has listed Medrol dosepak that was not taken prophylactically or for a SAR and is not a vaccine, it was taken from 02-07NOV2020, 4mg PO as directed X 6 days. Excedrin was not taken prophylactically or for a SAR and is not a vaccine, it ia ongoing starting from 26DEC2020, 325/500/65mg PO BID. Please ensure that all con meds listed in source are also documented in EDC.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:38:03
Query 'Con med list has listed Medrol dosepak that was not taken prophylactically or for a SAR and is not a vaccine, it was taken from 02-07NOV2020, 4mg PO as directed X 6 days.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:35:38

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Con med list has listed Medrol dosepak that was not taken prophylactically or for a SAR and is not a vaccine, it was taken from 02-07NOV2020, 4mg PO as directed X 6 days.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:35:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 12:16:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 12:16:03
Data point term sent to Coder	System	02 Nov 2020 15:31:31
User entered 'Albuterol'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'No (N)'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per CDM:Kindly do not close the query until data is updated.Thank you.' (Site from DM).	(b) (4)	07 Jan 2021 04:57:25
User closed query 'Per CDM Re-Query: Please keep Query open until resolution. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:57:23
Query 'Per CDM Re-Query: Please keep Query open until resolution. Thank you' answered with 'AE added' (Site from DM).	Amber Stanford (b) (4)	05 Jan 2021 23:20:32
Query 'Per CDM:Kindly do not close the query until data is updated.Thank you.' answered with 'AE updated' (Site from DM).	(b) (4)	05 Jan 2021 23:07:35
User opened query 'Per CDM Re-Query: Please keep Query open until resolution. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:17:45
User closed query 'Per DM CLR: Please note 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.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:17:45
User opened query 'Per CDM:Kindly do not close the query until data is updated.Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:42:15
Query 'Per DM CLR: Please note 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.' answered with 'AE documentation pending PI signature and then will complete reconciliation within EDC' (Site from DM).	Amber Stanford (b) (4)	28 Dec 2020 22:59:36
User opened query 'Per DM CLR: Please note 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.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:26:37

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'Wheezing'	Amber Stanford (b) (4) (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered '90'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'ug (ug)'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User entered empty.	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'as needed (PRN)'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User entered empty.	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User entered empty.	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered '27 Oct 2020'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered '0'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 18:39:54
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)	12 Feb 2021 03:24:32
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated' (Site from DM).	Amber Stanford (b) (4)	10 Feb 2021 22:37:42
DataPoint Un-verified.	Amber Stanford (b) (4)	10 Feb 2021 22:37:36
User entered 'No (N)' reason for change: Data Entry Error	Amber Stanford (b) (4)	10 Feb 2021 22:37:36
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)	10 Feb 2021 00:00:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered 'Yes (Y)'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	12 Mar 2021 18:39:53
DataPoint Un-verified.	Amber Stanford (b) (4)	10 Feb 2021 22:37:36
User entered '09 Nov 2020' reason for change: New Information	(b) (4)	10 Feb 2021 22:37:36
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:09:16
User entered empty.	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	18 Nov 2020 19:09:16
User entered 'No (N)'	Amber Stanford (b) (4)	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User entered empty.	System	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User entered empty.	System	02 Nov 2020 15:30:32

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:40
User entered empty.	System	02 Nov 2020 15:30:32

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE, PRODUCTS YNOM: MEDROL DOSEPAK - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 21:05:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Jan 2021 21:05:56
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:21:52
Data point term sent to Coder	System	11 Jan 2021 19:41:05
User entered 'MEDROL DOSE PACK'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'No (N)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 20:24:19
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 20:22:29
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:22:13
User entered 'Wheezing'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '4'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'mg (mg)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'once daily (QD)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '2 Nov 2020'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '0'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'No (N)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
	(b) (4), (b) (6)	
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	11 Jan 2021 19:40:55
User entered '7 Nov 2020' reason for change: Data Entry Error	Amy McMahan (b) (4)	11 Jan 2021 19:40:55
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	11 Jan 2021 19:40:43
User entered '7 Nov 2019'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'No (N)'	Amy McMahan (b) (4)	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User entered '1'	System	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User entered '1'	System	11 Jan 2021 19:40:43

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:44
User entered '804 (804)'	System	11 Jan 2021 19:40:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:37:55
User signature succeeded.	Richard Rupp (b) (4)	13 Apr 2021 13:21:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Apr 2021 09:11:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Apr 2021 09:11:02
Data point term sent to Coder	System	12 Apr 2021 17:00:40
User closed query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	System	12 Apr 2021 17:00:32
' (Site from System).		
Query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Amber Stanford (b) (4)	12 Apr 2021 17:00:32
' answered with 'Reconciled and updated' (Site from System).		
DataPoint Un-verified.	Amber Stanford (b) (4)	12 Apr 2021 17:00:19
Coding entries removed.	Amber Stanford (b) (4)	12 Apr 2021 17:00:19
Signature has been broken.	Amber Stanford (b) (4)	12 Apr 2021 17:00:19
User entered 'Acetaminophen/Aspirin/Caffeine' reason for change: Data Entry Error	Amber Stanford (b) (4)	12 Apr 2021 17:00:19
User opened query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	12 Apr 2021 08:52:45
' (Site from System).		
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 20:24:14
Query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' answered with 'added' (Site from CRA).	Kristin Pollock (b) (4)	09 Feb 2021 18:56:34
User opened query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:53:22
User closed query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 17:52:58
Query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' answered with 'AE form completed but pending PI signature. Will update EDC after signature is obtained' (Site from CRA).	Amber Stanford (b) (4)	28 Jan 2021 20:05:40
User opened query 'Per conmed log patient, pt took 10mg Ketorolac PO QID from 13-16JAN2021, it was not prophylactic, not a vaccine, and not taken for a solicited event. Please review con med log and update EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 16:50:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Jan 2021 00:08:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:08:11
	System	21 Jan 2021 16:48:43
	Amber Stanford (b) (4)	21 Jan 2021 16:47:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:22:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 19:43:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 19:43:41
Data point term sent to Coder	System	11 Jan 2021 19:43:06
User entered 'EXCEDRIN'	Amy McMahan (b) (4) (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'No (N)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:40:07
DataPoint Un-verified.	Amber Stanford (b) (4)	21 Jan 2021 16:47:59
User entered 'Symptomatic COVID19' reason for change: Data Entry Error	Amber Stanford (b) (4)	21 Jan 2021 16:47:59
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'HEADACHE'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '325/500/65'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'mg (mg)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'twice daily (BID)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'Oral (ORAL)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '26 Dec 2020'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered '0'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:40:20
DataPoint Un-verified.	Amber Stanford (b) (4)	20 Jan 2021 16:31:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 16:31:13
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:22:13
User entered 'Yes (Y)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	26 Jan 2021 16:40:30
DataPoint Un-verified.	Amber Stanford (b) (4)	20 Jan 2021 16:31:13
User entered '05 Jan 2021' reason for change: New Information	Amber Stanford (b) (4)	20 Jan 2021 16:31:13
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 20:22:13
User entered empty.	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	11 Jan 2021 20:22:13
User entered 'No (N)'	Amy McMahan (b) (4)	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User entered '2'	System	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User entered '1'	System	11 Jan 2021 19:42:46

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:45
User entered '804 (804)'	System	11 Jan 2021 19:42:46

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:13:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:13:52
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:24:19
Data point term sent to Coder	System	09 Feb 2021 18:57:45
User entered 'Ketorolac'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'No (N)'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4)	11 Mar 2021 06:22:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'AE updated' (Site from DM).	Amber Stanford (b) (4)	09 Mar 2021 20:22:20
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:58:59
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'Neck pain'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:13:07
User closed query 'Per Con med log, dose was 10mg. please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 17:13:04
Query 'Per Con med log, dose was 10mg. please review and update if needed.' answered with 'Updated' (Site from CRA).	Amber Stanford (b) (4)	09 Feb 2021 23:25:09
User entered '10' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 23:25:01
User opened query 'Per Con med log, dose was 10mg. please review and update if needed.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 21:22:11
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:31
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered '13'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'mg (mg)'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 20:24:19
User entered empty.	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'four times daily (QID)'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 20:24:19
User entered empty.	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'Oral (ORAL)'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 20:24:19
User entered empty.	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered '13 Jan 2021'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered '0'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	09 Feb 2021 20:24:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 18:57:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 18:57:35
User entered 'No (N)' reason for change: Data Entry Error	Kristin Pollock (b) (4)	09 Feb 2021 18:57:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 18:57:27
User entered empty.	System	09 Feb 2021 18:57:27
	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered '16 Jan 2021'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:24:19
User entered 'No (N)'	Kristin Pollock (b) (4)	09 Feb 2021 18:57:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User entered '4'	System	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User entered '1'	System	09 Feb 2021 18:57:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:19:50
User entered '804 (804)'	System	09 Feb 2021 18:57:27

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 17:53:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 20:07:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 20:07:41
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 20:06:14
User entered 'Metoprolol'	Amber Stanford (b) (4)	19 Mar 2021 20:05:27
	(b) (4)	

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Tachycardia'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '50'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'mg (mg)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'twice daily (BID)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Oral (ORAL)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '12 Feb 2021'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '0'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 20:05:27

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 20:05:27

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:48

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:31:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:31:37
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	29 Mar 2021 16:45:37
User closed query 'Per source, patient began taking Vitamin D3 5000IU orally daily, start date 12FEB2021, med is ongoing, not a vaccine and not prophylactic. ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	25 Mar 2021 21:29:51
Query 'Per source, patient began taking Vitamin D3 5000IU orally daily, start date 12FEB2021, med is ongoing, not a vaccine and not prophylactic. ' answered with 'reconciled and updated' (Site from CRA).	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:30:24
User opened query 'Per source, patient began taking Vitamin D3 5000IU orally daily, start date 12FEB2021, med is ongoing, not a vaccine and not prophylactic. ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	23 Mar 2021 17:57:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	23 Mar 2021 17:53:36
Data point term sent to Coder	System	19 Mar 2021 20:44:58
User entered 'Lisinopril'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Tachycardia'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '5'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'mg (mg)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'once daily (QD)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Oral (ORAL)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '12 Feb 2021'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered '0'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered empty.	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:53:36
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 20:44:02

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 20:44:02

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:09:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:09:52
Data point term sent to Coder	System	07 Apr 2021 15:08:10
Data point term sent to Coder	System	07 Apr 2021 15:07:09
Coding entries removed.	Amy McMahan (b) (4) (b) (4)	07 Apr 2021 15:06:57
User signature succeeded.	Richard Rupp (b) (4) (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	25 Mar 2021 21:29:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 20:27:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 20:27:30
Data point term sent to Coder	System	25 Mar 2021 20:26:54
User entered 'Vitamin D3'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:26:51
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:23:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:23:47
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
User closed query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4)	08 Apr 2021 06:02:40
DataPoint Un-verified.	Amy McMahan (b) (4)	07 Apr 2021 15:07:41
Signature has been broken.	(b) (4)	
	Amy McMahan (b) (4)	07 Apr 2021 15:07:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amy McMahan (b) (4)	07 Apr 2021 15:07:41
Query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4)	
	Amy McMahan (b) (4)	07 Apr 2021 15:07:13
User opened query 'Per DM CLR: Please review response as vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:50:03
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'No (N)'	Amber Stanford (b) (4)	25 Mar 2021 20:26:10
	(b) (4)	

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:23:53
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
User entered 'Supplement' reason for change: Data Entry Error	Amy McMahan (b) (4)	07 Apr 2021 15:07:41
DataPoint Un-verified.	Amy McMahan (b) (4)	07 Apr 2021 15:06:57
Signature has been broken.	Amy McMahan (b) (4)	07 Apr 2021 15:06:57
User entered 'Prophylaxis' reason for change: Data Entry Error	Amy McMahan (b) (4)	07 Apr 2021 15:06:57
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'Supplementation'	Amber Stanford (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered '5000'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'IU (IU)'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered empty.	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'once daily (QD)'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered empty.	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'Oral (ORAL)'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered empty.	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered '12 Feb 2021'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered '0'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'Yes (Y)'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered empty.	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

US3612031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:29:21
User entered 'No (N)'	Amber Stanford (b) (4) (b) (4)	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 20:26:10

**US3612031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 20:26:10

US3612031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:00:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:53:52
User entered 'No (N)'	Amy McMahan (b) (4) (b) (4)	04 Feb 2021 16:19:24

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'USA-US129-2021-MRNA-1273-P301000003'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:08
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Richard' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Richard'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Rupp' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Rupp'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '301 University Blvd'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Galveston'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Texas' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered 'NJ'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'TX'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '77555'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:55:42
User entered 'US'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 17:59:58
User entered '2'	System	22 Jan 2021 16:55:51
User entered '1'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'USA-US129-2021-MRNA-1273-P301000003'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:08
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Richard' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Richard'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Rupp' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Rupp'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '301 University Blvd'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Galveston'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Texas' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered 'NJ'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'TX'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '77555'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:55:42
User entered 'US'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 17:59:58
User entered '2'	System	22 Jan 2021 16:55:51
User entered '1'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
User entered '12/Jan/2021 12:37'	System	12 Jan 2021 17:37:16

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:00:48

**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.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:55:42
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'USA-US129-2021-MRNA-1273-P301000003'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:08
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Richard' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Richard'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Rupp' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Rupp'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '301 University Blvd'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Galveston'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Texas' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered 'NJ'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'TX'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '77555'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:55:42
User entered 'US'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 17:59:58
User entered '2'	System	22 Jan 2021 16:55:51
User entered '1'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
User entered '22/Jan/2021 16:55'	System	22 Jan 2021 16:55:51

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:00:48

**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.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 17:59:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 16:55:51

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'USA-US129-2021-MRNA-1273-P301000003'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'No (N)'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:08
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Richard' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Richard'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Rupp' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered (b) (6)'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Rupp'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '301 University Blvd'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'Galveston'	System	12 Jan 2021 17:36:54

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:48

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	09 Apr 2021 14:56:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:25:11
Signature has been broken.	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User entered 'Texas' reason for change: Data Entry Error	Kristin Pollock (b) (4)	06 Apr 2021 15:22:43
	(b) (4)	
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
	(b) (4)	
Un-reviewed for Safety.	System	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered 'NJ'	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered 'TX'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
Un-reviewed for Safety.	(b) (4)	23 Mar 2021 17:59:58
DataPoint Un-verified.	System	23 Mar 2021 17:59:58
User entered empty.	System	23 Mar 2021 17:59:58
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 17:37:07
User entered '77555'	System	12 Jan 2021 17:36:54

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:02:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 16:55:42
User entered 'US'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 23:00:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Mar 2021 17:59:58
User entered '2'	System	22 Jan 2021 16:55:51
User entered '1'	System	12 Jan 2021 17:37:16

**US3612031**

**Folder: SAE USA-US129-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 23:00:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered '23/Mar/2021 12:59'	(b) (4) System	23 Mar 2021 17:59:58

US3612031

Folder: SAE USA-US129-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 23:00:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:25:11
User signature succeeded.	Richard Rupp (b) (4)	29 Mar 2021 16:45:37
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 17:59:58